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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt

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Director

Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Original Holder of Assessment Certificate (First Applicant)

An Assessment Certificate for the notified chemical known by the name Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt was granted to Bayer Australia Limited (ACN 000 691 690) of 633 – 647 Springvale Road Mulgrave North VIC 3170.

The Assessment Report for Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt is identified by the sequence number STD/1018.

Second Applicant

Since granting of the abovementioned Assessment Certificate, Beiersdorf Australia Ltd of 4 Khartoum Road, North Ryde, NSW 2113 has submitted a notification statement in support of their application for an extension of the original Assessment Certificate for Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt. Bayer Australia Limited has agreed to this extension.

Information submitted by Beiersdorf Australia Ltd pertains to the introduction of the notified chemical for use in a cosmetic cream. The end use products will be distributed nation wide. Beiersdorf Australia Ltd will be importing 100 kg per year as the finished product.

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

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)
No.

NOTIFICATION IN OTHER COUNTRIES
EU (2000).

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt

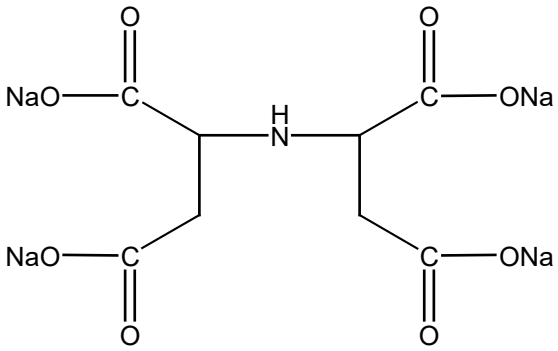
OTHER NAME(S)
IDS-Na Salt

MARKETING NAME(S)
Baypure CX 100 Solid

CAS NUMBER
144538-83-0

MOLECULAR FORMULA
$C_8H_{11}NO_8.4Na$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
337.1

SPECTRAL DATA

METHOD Infrared (IR) spectroscopy
Remarks Major absorbance peaks were observed at approximately 3422, 1577, 1401, 1313, 1202, 1128, 994, 934, 815 and 672 cm^{-1}. UV-Vis absorption and NMR spectra were also provided.

METHODS OF DETECTION AND DETERMINATION
IR, UV-Vis and NMR spectroscopy.

3. COMPOSITION

DEGREE OF PURITY
72.1%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

Chemical Name	fumaric acid, disodium salt		
CAS No.	17013-01-3	*Weight %*	5.6
Chemical Name	aspartic acid, disodium salt		
CAS No.	5598-53-8	*Weight %*	10.6
Chemical Name	water		
CAS No.	7732-18-5	*Weight %*	8.9

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Import.

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

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

USE
The notified chemical is a chelating agent to be used in formulations of non-caustic oven and grill cleaners for the commercial and consumer market and is not to be sold to the public. The end products are intended for industrial cleaning applications only in restaurants, cafes, and hotels.

In addition, Beiersdorf Australia Ltd will import the notified chemical at 100 kg per year. It will be imported as a component of cosmetic creams (typically 0.2%).

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne and Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
Diversy Lever Australia, 29 Chifley St, Smithfield, NSW 2164.
Beiersdorf Australia Ltd, 4 Khartoum Road, North Ryde, NSW 2113.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported into Australia in 260 kg plastic drums as a 34% and 40% aqueous solution.

The notified chemical will be imported as a component of finished and packaged product. The product will be introduced in two packaging sizes. 50 mL jar and 15 mL face mask.

5.2. Operation Description

At the manufacturing site, the notified chemical is pumped from the storage containers into a mixing tank, where it is mixed with other components. The finished product is pumped from the mixing vessel to a piston operated filling unit, which automatically fills and caps the 2 L, pre-labelled containers. The final concentration of the notified chemical in the oven cleaning products ranges between 2.5 and 9.5%. The containers are packed into cartons and loaded onto pallets for storage in a bunded warehouse prior to being sold to customers.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage	6 – 8	4 hours/day	100 days/year
Production	15	4 hours/day	50 days/year
Technical	3	1 hour/day	50 days/year
Sales	100	1 hour/day	250 days/year
End users	5000	1 hour/day	250 days/year

Exposure Details
Waterside workers, truck drivers and warehouse workers should only be exposed to the notified chemical in the event of an accident.

The notified chemical will be pumped to one of four stainless steel water jacketed vessels (1800, 5500

or 8000 L) using air operated diaphragm pumps. Other components and water are added and the final concentration of the notified chemical is 2.2 – 9.5%. The area above the mixing vessels will be ventilated through an extractor and the entire blending process is undertaken within closed loop systems with local and general ventilation. After mixing the product is automatically filled into 2 L bottles which are capped automatically. Exposure may be possible to drips and spills when connecting and disconnecting lines while pumping and during system cleaning and maintenance. Inhalation exposure is unlikely. Production personnel wear overalls, PVC coated cotton gloves, safety glasses and protective footwear at all times.

Technical staff may be exposed to small amounts when checking raw materials or finished goods for compliance with specifications. Samples of the raw material are taken from the drum using a dipper and transferred to a labelled plastic container and the final product is sampled via a sample port in the batch tank to a plastic container. All laboratory work will be conducted in fume cupboards and technical staff wear gloves and safety glasses when handling chemicals.

Sales personnel will demonstrate the finished product to restaurants, cafes and hotels. Workers in cafes and restaurants are expected to apply the finished products according to the instructions on the label.

Beauticians and beauty salon personnel will be in contact with the cream containing the notified chemical**.**

5.4. Release

RELEASE OF CHEMICAL AT SITE

At the manufacturing site, the mixing tanks are cleaned after each batch. Cleaning involves hosing the tank walls with a high-pressure water gun. The resulting washings are drained to the on-site trade waste pit and subsequently to a holding tank prior to treatment. Treatment consists of pH correction, using phosphoric acid, to between 7-10 according to the company's agreement with Sydney water, which is tested for compliance every 22 days. The pH corrected waste passes to a conical bottomed sedimentation tank from which the precipitated solids are removed daily. Treated trade waste is then released into the Metropolitan sewer.

The notifier indicated that, owing to the high water solubility of the notified chemical, the treatment process is not expected to remove much of the chemical, prior to release into the sewer. The daily volume of trade waste is 1500 L. The notifier estimates that 1% of the import volume of the chemical is washed into the on-site treatment each year as a result of tank cleaning, equating to about 40 kg per year.

RELEASE OF CHEMICAL FROM USE

At end user sites, it is expected that the majority of the notified chemical will end up in the sewer after cleaning of ovens, grills and fryers, when soiled scourers or equipment is rinsed with water and the water discarded down the sink. For ovens and grills, a spraying lance with a foam nozzle is used on a surface (max 70ºC). After 5-30 minutes a scourer is used to remove soiling, and rinsed thoroughly. Fryers are filled with cleaning solution, heated up to 100ºC for 20-60 minutes and then filled with water, and rinsed thoroughly. Assuming usage of all of the maximum import volume is averaged over a whole year, then the daily release of the notified chemical into the domestic sewer will be approximately 10 kg.

5.5. Disposal

Disposal of chemical wastes generated from spills and container residues (expected to be about 40 kg/annum) during manufacturing is expected to occur through licensed waste contractors. Most wastes are expected to end up in landfill as solid waste.

5.6. Public exposure

The notified chemical is an ingredient of cosmetic creams intended for consumer use. Public exposure to the notified chemical via the skin can be expected to be widespread. The notified chemical has negligible volatility and is unlikely to be inhaled. The potential for public exposure to the notified chemical is therefore high, although the concentration of notified chemical is cosmetic creams is low at 0.2% (typical).

Public exposure to the notified chemical through its use in industrial cleaning solutions is limited as the products will not be available to the public.

The public may be exposed to the notified chemical through transport accidents and environmental contamination, although such events are unlikely.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White solid.

Boiling Point > 300°C at 101.3 kPa

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks No melting of the test substance was detected up to the limit of the method.
TEST FACILITY Bayer (1997a).

Density 740 kg/m^3

Vapour Pressure 1.5 X 10^{-16} kPa at 20°C.

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks The vapour pressure of the test substance was measured using a vapour pressure balance at temperatures ranging between 79.7 and 237.6°C. The vapour pressure at 20°C was extrapolated using the Antoine equation. The results indicate the test substance is not volatile as would be expected for a tetra sodium salt.
TEST FACILITY Bayer (1997b)

Water Solubility 564 g/L at 25°C and pH 13.1.

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks The water solubility of the test substance was determined by capillary electrophoresis. Preparation of the sample involved mixing three replicates samples containing 558, 572 and 562 g/L of the test substance with a 5 mmol buffer (1,2,4,5-Benzenetetracarboxylic acid and modifier) in flasks prior to agitating for 24, 48, and 72 hours at 30°C, and then a further 24 hours at 20°C. The results indicate the test material is readily soluble in water.
TEST FACILITY Bayer (1997c)

Hydrolysis as a Function of pH Not determined.

Remarks The notified chemical does not contain any hydrolysable groups.

Partition Coefficient (n-octanol/water) Not determined.

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks It was not possible to determine the partition coefficient of the notified chemical because of the inability to determine the pH at which the unionised form exists. It is assumed that this is < 2, and therefore not relevant to environmental conditions. Given the chemical's high water solubility, it is expected to be lipophilic. A value of –3.93 was estimated by the fragment method.
TEST FACILITY Bayer (1997d).

Adsorption/Desorption Not determined.

Remarks On the basis of the high water solubility, and the fact that the chemical occurs in ionised form at pH 4-9, the notified chemical is not expected to adsorb to organic matter in soils. However, the chemical may form complexes with mineral matter.

Dissociation Constant Not determined.

Remarks The notified chemical fully dissociates at environmental pH ranges.

Particle Size Volume weighted mean: 161 μm; Surface weighted mean: 86 μm.

METHOD Not stated.

Range (μm)	*Mass (%)*
< 67	10
< 145	50
< 281	90

Remarks Analysis performed using a Mastersizer 2000.

Flash Point Not applicable.

Flammability Limits Not flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
TEST FACILITY Bayer (1997e).

Pyrophoric Properties Not pyrophoric.

METHOD EC Directive 92/69/EEC A.13 Pyrophoric properties (Solids).
TEST FACILITY Bayer (1997e).

Autoignition Temperature 330°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY Bayer (1997e).

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
TEST FACILITY Bayer (1997e).

ADDITIONAL TESTS

Oxidising Properties No oxidising properties.

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
TEST FACILITY Bayer (1997e).

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation
Rat, oral repeat dose toxicity - 28 days.	NOEL = 200 mg/kg/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo micronucleus test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Iminodisuccinic acid, sodium salt.

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/Wistar.
Vehicle Administered as a 20% solution.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3/sex	2000	None.

LD50 > 2000 mg/kg bw
Signs of Toxicity None.
Effects in Organs None.

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY Bayer AG (1996a).

7.2. Acute toxicity - dermal

TEST SUBSTANCE Iminodisuccinic acid, sodium salt.

METHOD EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain Rat/Wistar.
Vehicle Tap water.
Type of dressing Semi-occlusive.
Remarks - Method Number of animals was limited by reference to OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. As the pH of the paste was above 11, one male initially received the intended dosage. The study was continued when neither systemic effects nor skin corrosivity were observed.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3/sex	2000	None.

LD50 > 2000 mg/kg bw
Signs of Toxicity - Local In female rats only: reddening of the skin (2/3, day 2), encrustation (3/3, days 2 to 5).
Signs of Toxicity - Systemic In female rats only: high legged gait (1/3, 10 – 30').

Effects in Organs	None.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Bayer (1997f).

7.3. Acute toxicity - inhalation

Data not provided.

7.4. Irritation – skin

TEST SUBSTANCE	Iminodisuccinic acid, sodium salt.
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/Himalayan White.
Number of Animals	3 males.
Vehicle	Water.
Observation Period	3 days.
Type of Dressing	Semi-occlusive.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0	-	0
Oedema	0	0	0	0	-	0

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

CONCLUSION	The notified chemical is non-irritating to skin.
TEST FACILITY	LPT (1998a).

7.5. Irritation - eye

TEST SUBSTANCE	Iminodisuccinic acid, sodium salt.
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/Himalayan White
Number of Animals	3
Observation Period	3 days.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0	0	0	-	0
Conjunctiva: chemosis	0	0	0	0	-	0
Conjunctiva: discharge	0	0	0	0	-	0

Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results

CONCLUSION The notified chemical is non-irritating to the eye.

TEST FACILITY LPT (1998b).

7.6. Skin sensitisation

TEST SUBSTANCE Iminodisuccinic acid, sodium salt.

METHOD OECD TG 406 Skin Sensitisation – maximisation test.
EC Directive 96/54/EC B.6 Skin Sensitization – maximisation test.

Species/Strain Guinea pig/Hsd Poc:DH.

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 1% produced reddened weal after 24 and 48 hours.
topical: 20%

MAIN STUDY

Number of Animals Test Group: 20 Control Group: 10

INDUCTION PHASE Induction Concentration:
intradermal injection, 1%
topical application, 25%

Signs of Irritation

CHALLENGE PHASE

1st challenge topical application: 20%

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	20%	0/20	0/20	-	-
Control Group	20%	0/10	0/10	-	-

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY Bayer AG (1997g).

7.7. Repeat dose toxicity

TEST SUBSTANCE Iminodisuccinic acid, sodium salt.

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain Rat/Wistar.

Route of Administration Oral – gavage.

Exposure Information Total exposure days: 28 days;
Dose regimen: 7 days per week;
Post-exposure observation period: 14 days.

Vehicle Water

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	None.
II (low dose)	"	40	"
III (mid dose)	"	200	"
IV (high dose)	"	1000	"
V (control recovery)	"	0	"
VI (high dose recovery)	"	1000	"

Mortality and Time to Death

None.

Clinical Observations

Lower motor activity was observed in high dose males.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No significant findings. A reduction in levels of alanine aminotransferase was noted in high dose males but no dose-relationship was observed.

Effects in Organs

High dose recovery animals exhibited lower relative thymus weights, an effect not observed in the high dose treatment group. No effects were noted at necropsy or on histopathological examination.

Remarks – Results

The lower relative thymus weights in the high dose recovery animals was not correlated with any other indicators of immunotoxicity and was, therefore, judged to be of limited toxicological significance.

The lower motor acitivity in high dose males was judged to have limited significance as there was no other indicator of neurotoxicity and there was a high variability in scores.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 200 mg/kg bw/day in this study, based on an effect on motor activity in high dose males.

TEST FACILITY Bayer AG (1997h).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE Iminodisuccinic acid, sodium salt.

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102.
Metabolic Activation System	Rat liver S9 microsomal fraction.
Concentration Range in Main Test	a) With metabolic activation: 50 – 5000 µg/plate. b) Without metabolic activation: 50 – 5000 µg/plate.
Vehicle	Not stated.
Remarks - Method	A 20' preincubation step was included prior to plating.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	5000			- ve
Test 2				-ve
Present				
Test 1	5000			-ve
Test 2				-ve

Remarks - Results

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

TEST FACILITY Bayer AG (1997i)

7.9. Genotoxicity – in vivo

TEST SUBSTANCE Iminodisuccinic acid, sodium salt.

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain Mouse/Hsd/Win: NMRI.
Route of Administration Intraperitioneal.
Vehicle Deionised water.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
1	5/sex	0	24
2	"	1500	16
3	"	1500	24
4	"	1500	48
5	"	CP, 20	24

CP=cyclophosphamide.

RESULTS
Doses Producing Toxicity 1500 mg/kg bw. Compound related symptoms demonstrated that the test substance was absorbed.
Genotoxic Effects None.

CONCLUSION The notified chemical was not clastogenic in this in vivo micronucleus test under the conditions of the test. The ratio of polychromatic to normochromatic erythrocytes was not altered by the test compound and the frequency of micronucleated polychromatic erythrocytes was not elevated.

TEST FACILITY Bayer AG (1997j).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	IDS, sodium salt
METHOD	OECD TG 301E Ready Biodegradability: Modified OECD Screening Test.
Inoculum	Activated sludge from sewage effluent.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved Organic Carbon (DOC)
Remarks - Method	Microorganisms were exposed to an amount of test substance, equivalent to 19.8 mg/L DOC. Testing involved seven test flasks, 2 containing test substance, inoculum and a mineral medium, 2 containing a reference substance (aniline), 2 containing only inoculum and a mineral medium, and one toxicity control. Biodegradation rates were monitored in each test flask by determining the DOC ratios at intervals over the test period.

RESULTS

Test substance		*Aniline*	
Day	*% degradation*	*Day*	*% degradation*
7	77	7	94
28	79	28	97

Remarks - Results	The precent degradation in the toxicity control reached 88% after 28 days indicating no toxicity effects.
CONCLUSION	Over 70% of the notified chemical was degraded within the first 10 days, therefore it is classified as readily biodegradable.
TEST FACILITY	Bayer (1997k)

8.1.2. Inherent biodegradability

TEST SUBSTANCE	IDS Na4 (EA 36615)
METHOD	OECD TG 302B Inherent Biodegradability: Zahn-Wellens/EMPA Test.
Inoculum	Activated sludge from sewage effluent.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved Organic Carbon (DOC)
Remarks - Method	A mixture containing the test substance, equivalent to 92.4 mg/L, mineral nutrients, and activated sludge (0.4 g dry matter/L) in aqueous media was agitated and aerated at 20-25°C. Blank controls containing a reference substance, mineral nutrient, and inoculum were run in parallel. Biodegradation was monitored by determining the DOC in filtered samples at 0 and 3 hours, and 1, 7, 14, 21 and 28 days. The ratio of eliminated DOC to initial DOC (corrected for blanks) was expressed as a percentage of biodegradation.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*
1	14	1	26
7	78	7	99

28	99	28	100

Remarks - Results	The precent degradation in the toxicity control reached 99% after 28 days indicating no toxicity effects.
CONCLUSION	The notified chemical is inherently biodegradable.
TEST FACILITY	Bayer (2000a)

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	IDS, sodium salt.
METHOD	EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - static test conditions.
Species	*Brachydanio rerio*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	TOC % at 0, 24, 48, 72, and 96 hours.
Remarks – Method	Fish were exposed to 100 mg/L of test substance. No details are provided on the number of fish or replicates used in the test. No information is provided on the methods of determination of the LC0 value.
RESULTS	
LC0	≥82.6 mg/L mg/L at 96 hours.
NOEC	>82.6 mg/L
Remarks – Results	No fish exposed to the test substance died during the test.
CONCLUSION	The test substance is very slightly toxic to Zebra fish (Mensink *et al*. 1995).
TEST FACILITY	Bayer (1997l).

8.2.2. Chronic toxicity to fish

TEST SUBSTANCE	IDS, sodium salt.
METHOD	OECD TG 204 Fish, Prolonged Toxicity Test: 14 day Study.
Species	*Brachydanio rerio*
Exposure Period	14 days
Auxiliary Solvent	None
Water Hardness	248.1 mg/L $CaCO_3$ (day 0), 262 mg/L (day 7) $CaCO_3$
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks – Method	Groups of 10 fish (the number of replicates used is not clear) were exposed to nominal test concentrations of 0 (control), 1.0, 3.16 and 10 mg/L of test substance for a period of 14 days. The test medium was renewed 3 times per week. The highest test concentrations were verified by TOC analysis 3 times per week. Measured concentrations ranged from 70-210% of nominal. However, only one sample each was measured at the lowest and highest end of the range. Average measured concentrations were within 114% of nominal.
RESULTS	
NOEC	≥10 mg/L at 14 days (nominal concentrations) ≥12 mg/L at 14 days (arithmetic mean of analytical values)

Remarks – Results	No fish died or exhibited abnormal behaviour over the test period.
CONCLUSION	The test substance is very slightly toxic to Zebra fish (Mensink *et al*. 1995).
TEST FACILITY	Bayer (2000b).

8.2.3. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	IDS, sodium salt
METHOD	EC Directive 92/67/EEC Part A/172 Acute Toxicity (immobilisation) for Daphnia - static test conditions.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks - Method	No details were provided on the number of test organisms or replicates used in the test. Daphnia were exposed to test concentrations of 0 (control) and 100 mg/L of test substance, equivalent to 28.6 mg/L TOC. Test concentrations were verified at 0 and 48 hours. Concentrations of the test substance remained between 78 and 91% nominal. No details were provided on how the endpoints were calculated.
RESULTS	
EC0	≥ 84 mg/L at 48 hours
Remarks - Results	No *Daphnia* were immobilised over the test period.
CONCLUSION	The test substance is very slightly toxic to *Daphnia* (Mensink *et al*. 1995).
TEST FACILITY	Bayer (1997m).

8.2.4. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	IDS, sodium salt
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – semi-static conditions.
Species	*Daphnia magna*
Exposure Period	21 days
Auxiliary Solvent	None
Water Hardness	276.7-274.9 mg $CaCO_3$/L
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks - Method	Ten daphnids each (1 daphnid X 10 reps) were exposed to test concentrations of 0 (control), 0.1, 0.32, 1.0, 3.2 and 10 mg/L of test substance for a period of 21 days. The number of immobilised *Daphnia* was recorded 3 times per week, and after the onset of reproduction, the number of living offspring was recorded 3 times per week. Test concentrations of the highest exposure level were verified by TOC determination at each renewal and after 48 or 72 hours respectively. It is not clear from the test report how often the test media was renewed. Immobilisation and reproduction rates were determined by statistical analysis.
RESULTS	
LC0	≥11.7 mg/L at 21 days (immobilisation and reproduction)
NOEC	≥11.7 mg/L at 21 days (reproduction)
Remarks - Results	There was no statistically significant difference in the immobilisation and

reproduction rates between the control and the test media.

CONCLUSION The test substance is very slightly toxic to *Daphnia* (Mensink *et al*. 1995).

TEST FACILITY Bayer (2000c).

8.2.5. Algal growth inhibition test

TEST SUBSTANCE IDS, sodium salt

METHOD EC Directive 67/548/EEC Part A/179 Algal Inhibition Test.

Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range Nominal	0 (control) 6.3, 12.5, 25, 50, and 100 mg/L
Concentration Range Measured	7 to 94.5 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	TOC, cell densities, pH
Remarks - Method	Algal cells were exposed to the above nominal test concentrations over a 72 hour period, and cell counts were conducted at 24, 48 and 72 hours. The pH was measured at the start and end of the test, and ranged between 8.3 and 10.4, thus deviating by more than 1 unit in the control and test concentrations below 25 mg/L, possibly due to the rapid algal growth. Test concentrations were verified by TOC analysis at 0 and 72 hours. The concentrations ranged between 84 and 168 % of nominal. End points were determined using the arithmetic mean of analytical TOC values, multiplied by a factor of 3.5 (1 mg/L TOC = 3.5 mg/L of test substance).

RESULTS

Endpoint	*mg/L at 72 h*	
	Biomass	*Growth*
EC10	*22.4*	*>22.8 and <45.5*
EC50	66.5	94.5
NOEC	22.8	
LOEC	45.5	

Remarks - Results The percentage algal growth inhibition was 33.3% of the controls in the test media containing 50 and 100 mg/L nominal concentrations. The percentage inhibition of biomass growth was 52 and 57% respectively in the test media containing 50 and 100 mg/L nominal concentrations, and biomass growth inhibition was minimal (<3%) of the control in the other test media after 72 hours.

CONCLUSION The test substance is slightly toxic to algae (Mensink *et al*. 1995).

TEST FACILITY Bayer (1997n).

8.2.6. Inhibition of microbial activity

No test was provided on the inhibition of microbial activity by the notified chemical. However, no inhibitory effects were observed on sewage microorganisms in either the ready or inherent biodegradability test. Hence the test substance is not expected to be toxic to sewage microorganisms.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is a component in oven and grill cleaners, and hence, ultimately all of the imported volume of the chemical could enter the aquatic environment when the cleaning products or scouring pads are rinsed down the sink and into the sewer during cleaning application. The calculated daily nationwide predicted environmental concentration (PEC) of the notified chemical in the sewer is 3.9 X 10^{-3} µg/L. This value assumes: (1) all of the maximum import volume is used evenly over a 365 day period; (2) use is nationwide, with a population of 19 million contributing 150 L of water per person per day, and (3) there is no adsorption or loss of the chemical prior to release into the sewer.

The notified chemical is not volatile, is highly water soluble, and therefore is expected to partition mainly into the aquatic compartment. However, owing to its chelating ability, the chemical is expected to have a high affinity to the metal cations in the sewer and in soils and sediments, and hence some of the chemical may form insoluble precipitates that will settle out into sludge. The chemical is biodegradable, with 79% being degraded in a ready biodegradation test and some biodegradation may also occur in the sewer.

The notified chemical would pass through sewage treatment works having only primary levels of treatment, but is likely to partition into sludge in treatment works with secondary and tertiary level treatments, where it would form complexes with the various treatment chemicals. In the natural aquatic environment, the chemical is also expected to partition into sediments, most likely through complexing with Ca^{2+} and Mg^{2+} and other mineral cations in the water column and on the surfaces of suspended sediments. In soil/sediment environments the chemical is expected to be immobile and to undergo fairly rapid biodegradation.

9.1.2. Environment – effects assessment

The notifier submitted acute and chronic toxicity tests for fish and daphnia, and an acute test for algae. From these data, a predicted no effect concentration (PNEC) can be determined by taking the LC_{50} value of the most sensitive species, and dividing this value by an assessment safety factor. The submitted studies indicate that the most sensitive species is the freshwater algae, *Scenedesmus subspicatus,* having a 72 hour EC_{50} of 66.5 mg/L. Therefore, using this value and a worst-case scenario safety factor of 100 (OECD), the $PNEC_{aquatic}$ is 670 µg/L.

9.1.3. Environment – risk characterisation

The daily PEC of the notified chemical in the sewer of 3.9 X 10^{-3} µg/L. This value assumes all of the maximum import volume is used nationwide, over a 365 day period; a population of 19 million contributes 150 L of water per person per day, and there is no adsorption or loss of the chemical prior to release into the sewer. The concentration in effluent would be reduced once released into the receiving waters by an amount depending on whether it is released into the ocean or into a river. In a large coastal city it is assumed that the sewage effluent is diluted by a factor of 10 after discharge into the ocean, while a dilution factor of 3 is assumed for rural areas, thus resulting in PECs of 4 X 10^{-4} µg/L and 1.3 10^{-3} µg/L, respectively.

The PEC/PNEC ratios in the sewer (5.8 X 10^{-6}), and in the natural aquatic environment (1.9 X 10^{-6} and 5.9 X 10^{-7}), using algae as the most sensitive species, are all much less than 1, indicating no immediate concern for aquatic organisms.

No significant increase in the potential environmental impact will occur for the proposed extension of use. The extension indicates only minor projected increases of 50-100 kg/yr of the notified chemical, over two years, from an original annual usage of 3-4 tonnes per annum. The new use is expected to raise the nationwide PEC by 9.4 × 10^{-5} µg/L from the original estimate of 3.9 × 10^{-3} µg/L resulting in a new PEC of 3.99 × 10^{-3} µg/L. The new PEC is four orders of magnitude lower than the EC_{50} of the most sensitive species (EC_{50} = 66.5 mg/L).

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and storage workers should potentially only be exposed infrequently in the event of an accident.

Production personnel should only be potentially exposed infrequently to drips and spills during transfer operations and wear overalls, PVC coated cotton gloves, safety glasses and protective footwear to control exposure. Technical personnel may be exposed to small samples of the notified chemical and formulated products containing at a level of up to 9.5%. They wear gloves and safety glasses to control exposure. Sales personnel may be exposed to products containing the notified chemical during demonstrations but would normally be wearing gloves to prevent dermal contamination.

In the case of beauticians and salon personnel, skin contact with the notified chemical is possible during opening and closing of containers and during application. Workers will use gloves. Exposure will be low due to the low concentration of notified chemical in the cosmetic cream (typically 0.2%). The chemical is of low toxicity. Also, the concentration of the notified chemical is low. Therefore, OHS risk is low.

9.2.2. Public health – exposure assessment

Neither the notified chemical nor products containing it will be sold directly to the general public. Therefore exposure of the general public is not expected.

The notified chemical will be used by general public as an ingredient of a cosmetic cream. Therefore, the route of public exposure to the notified chemical is dermal. However, exposure will be low due to the low concentration of chemical in the cream.

9.2.3. Human health - effects assessment

The notified chemical was of low acute oral and dermal toxicity in rats (LD_{50} > 2000 mg/kg in both cases), was not irritating to skin or eyes in rabbits and was neither mutagenic in bacteria nor clastogenic in mouse bone marrow cells. The NOEL in a 28-day oral repeated dose study in rats was 200 mg/kg/day based on effects on motor activity at a higher dose.

The notified chemical would not be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

9.2.4. Occupational health and safety – risk characterisation

Given the low hazard of the notified chemical and likely low exposure to all groups of workers, the risk of adverse health effects is considered to be negligible.

9.2.5. Public health – risk characterisation

The chemical is of low toxicity and will be present in very low concentration. Therefore, public health risk is low.

Industrial cleaners containing the notified chemical will not be sold to the public so the risk to the public arising from this use is low.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratios: The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is low concern to public health.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and a product containing the chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

A Material Safety Data Sheet for Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt was provided by Beiersdorf Australia Ltd in a format consistent with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 1994b). The accuracy of this information remains the responsibility of the applicant.

11.2. Label

The label for a product containing the chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

CONTROL MEASURES

Occupational Health and Safety

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of through licensed waste contractors.

Emergency procedures

- Spills/release of the notified chemical should be collected and placed into sealed containers for disposal through approved waste disposal facilities.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:

- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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