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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Copolymer in Dodiflow V4313

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Copolymer in Dodiflow V4313

1. APPLICANT

Hoechst Australia of 606 St. Kilda Road, MELBOURNE, VIC 3004 and BetzDearborn Australia Pty. Ltd. of 69-77 Williamson Road, INGLEBURN, NSW 2565 have submitted a limited notification statement in support of their application for an assessment certificate for Copolymer in Dodiflow V4313.

2. IDENTITY OF THE CHEMICAL

Copolymer in Dodiflow V4313 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, some trade names of formulations, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the polymer composition and details of exact import volume and customers and site details have been exempted from publication in the Full Public Report and the Summary Report.

2. IDENTITY OF THE CHEMICAL

Other name:	N-stearyl maleimide octadecyl copolymer
Trade Name:	Dodiflow V4313, Dodiflow 4313 (imported product) Dodiflow V4313-1 Conc. (technical grade)
Number-Average Molecular Weight (NAMW):	> 1 000
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	0%
Molecular Weight < 1 000:	< 2%

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	yellow waxy solid with an oil-like odour
Boiling Point:	pour point 27°C (technical grade formulation)
Density:	870 kg/m^3 at 60°C (technical grade formulation)
Vapour Pressure:	not available
Water Solubility:	0.07 g/litre
Partition Co-efficient (n-octanol/water):	not available
Hydrolysis as a Function of pH:	not available
Adsorption/Desorption:	not available
Dissociation Constant:	not available
Flash Point:	~70°C; for imported product, ~60°C
Flammability Limits:	for imported product: Upper Explosive Limit = 0.6% Lower Explosive Limit = 6.5%
Autoignition Temperature:	not available
Explosive Properties:	see flammability limits
Reactivity/Stability:	no decomposition is expected if used as recommended; for the imported product carbonic acid may be split off at > 200°C

Comments on Physico-Chemical Properties

The water solubility determination was made on a sample of Dodiflow V4313 from which the solvent had been removed. This sample was suspended in water and stirred for 24 hours. The aqueous phase was separated without filtering and the water solubility determined by weighing the residue after evaporation of the water. This method of determination is not substance-specific and as such can cause large errors in the measured solubility with the weighed residue not necessarily being representative of the sample tested. Hence, the value quoted for the water solubility represents an upper limit. Based on its structure, it is anticipated that the actual solubility of the polymer will be much less.

Hydrolysis, partition coefficient, adsorption/desorption and dissociation constant have not been determined due to the moderately low solubility of the polymer. This is acceptable for the following reasons:

(i) hydrolysis of the linkages of the polymer would not be expected under environmental conditions;
(ii) given the expected low solubility in water it is anticipated that the partition coefficient for the polymer would be high and difficult to measure; and
(iii) on the basis of the polymer's relatively low water solubility it is likely to adsorb to, or be associated with soil/sediment and organic matter and be immobile in soil.

The polymer contains no acidic or basic functional groups.

4. PURITY OF THE CHEMICAL

Toxic or Hazardous Impurities: none

5. USE, VOLUME AND FORMULATION

The notified copolymer will be used as a component of a diesel fuel additive. It will be imported as a component of Dodiflow V4313. This will be blended into another product which will be used as diesel cloud point depressant.

It is expected that greater than 1 tonne of the notified copolymer will be imported per annum for the next five years.

6. OCCUPATIONAL EXPOSURE

The notified copolymer will be imported as a component of Dodiflow V4313 in either 200 L drums. Occupational exposure during transport and warehousing will be unlikely and will only occur in the event of leakage or accidental release.

Occupational exposure to the notified copolymer will be greatest when reformulating the Dodiflow V4313. This will be blended with other liquids to form a product that will be supplied to diesel fuel producers who will dose it into the fuel stream. This product is formulated by a blending operator at BetzDearborn's facility. The chemical mixing vessel is in a dedicated mix/blending room fitted with exhaust ventilation.

The product containing the notified copolymer will be used at up to 5 refineries where it will be automatically dosed into diesel fuel. Up to 10 personnel/ refinery could potentially be exposed to the notified copolymer. These staff range from shift operators on the crude distillation unit to maintenance personnel and laboratory analysts. In addition BetzDearborn staff from the Hydrocarbon process group and delivery specialists may be exposed to the notified chemical at the refinery.

At the refinery the product dosing is checked and adjusted every 2 to 4 hours during dosing. The injection pump is fully enclosed and the dosing is visually checked using a sight glass. These procedures take about 30 minutes. Samples are also taken once or twice/shift; this procedure takes about ten minutes. The main exposure pathways for staff involved in dosing would be inhalational or dermal. Maintenance fitters connect and disconnect the feed system and also undertake maintenance of the mixing equipment and pumps; there is therefore a high likelihood of exposure to the notified copolymer. This exposure is likely to be either inhalational if ventilation is inadequate, ocular or dermal. Laboratory personnel may also be exposed to the notified polymer during handling, although this will be limited through the use of laboratory fume hoods.

Occupational exposure to the notified copolymer in the finished product will be limited by the low concentration in diesel fuel.

7. PUBLIC EXPOSURE

The general public will not be exposed to Dodiflow V4313 or concentrated diesel additives containing the notified copolymer during storage and handling. The diesel additives containing the notified copolymer are dosed at a level resulting in a low concentration of the notified copolymer in diesel fuel. Finished diesel product is transported from refineries via road, rail or pipeline. The notifier has procedures for cleanup in the event of spillage, which should minimise the potential for exposure. During normal use of treated diesel fuels, the new polymer will be degraded as part of the combustion process in diesel engines before release, mainly in the form of elemental oxides, to the environment.

The use and release to the environment of the notified copolymer are not expected to present any significant public health hazard.

8. ENVIRONMENTAL EXPOSURE

Release

The product Dodiflow V4313 imported into Australia in 200 L drums will contain the notified polymer as a 50% solution. The notifier estimates the empty drums will contain a maximum of 0.5 kg of the polymer. The drums containing the notified polymer will be sent to a certified drum recycler where they will be rinsed and the rinsate disposed of according to government regulations through the Lidcombe aqueous waste treatment plant. It is anticipated that the waste polymer will be part of solid wastes from the Lidcombe treatment plant that will be consigned to landfill.

Waste generated in the reformulation of the imported product into the additive (from the rinsing of plant vessels) will be transported to the Lidcombe aqueous waste treatment plant and consigned to landfill as solid waste from the treatment

plant. The notifier estimates that the maximum amount of waste generated as a result of rinsing will be 1 000 kg.

Containers used to transport and store the additive, will be continually refilled without rinsing. Thus, there will be minimal release of the notified polymer to the environment. Similarly containers used in the storage and transport of the diesel fuels will be reused without rinsing also resulting in minimal release of the notified polymer.

The notified polymer is intended for use in diesel fuels as a cloudpoint depressant. As such its use will be widespread in boats, trucks and buses. It will be incorporated into the diesel fuels at refineries. The concentration of the additive in the fuels will be low. Spills and leaks (during handling eg. filling tanks and transport vehicles) or incomplete combustion of the diesel fuel blends may lead to minor releases of the notified polymer. Any such releases are expected to be well dispersed and at low levels.

Fate

The additive will be used in diesel fuels and will share their fate. Therefore, most will be combusted and destroyed in use. Complete combustion of the polymer will result in water and oxides of carbon and nitrogen.

A small amount of polymer will be consigned to landfill each year as rinsings from the import containers and the reformulation of the imported product into the additive. In landfill, it is anticipated that the relatively low water solubility of the polymer will mean it will remain immobile, being adsorbed to soils.

A minor component will be released to the environment from spills during transfers and leaks from tanks etc., and incomplete combustion, but would be widely dispersed. Any additive present in spills on road surfaces, or emissions, would be at low concentrations. If the polymer was washed off road surfaces, it would be expected to adsorb to soils or sediments adjacent the road. Emissions of the polymer are also expected to become associated with the soil compartment on the roadside.

Biological membranes are not permeable to polymers of very large molecular size and therefore bioaccumulation of the notified polymer is not expected {Anliker, 1988 #2; Gobas, 1986 #6}.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of *Dodiflow V4313-1 Conc.

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	{Hoffman, 1995 #95}
skin irritation	rabbit	slight irritant	{Kreiling, 1995 #96}
eye irritation	rabbit	slight irritant	{Kreiling, 1995 #97}

*technical grade Dodiflow V4313-1 Conc. contains the notified copolymer at 30 to 60%

9.1.1 Oral Toxicity {Hoffman, 1995 #95}

Species/strain:	rat/Wistar/ Hoe:WISKf(SPF71)
Number/sex of animals:	5 males/5 females
Observation period:	15 days
Method of administration:	orally
Clinical observations:	animals showed squatting posture, stilted and uncoordinated gait, irregular respiration; development of body weight was not impaired
Mortality:	nil
Morphological findings:	nil
Test method:	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
LD_{50}:	> 2 000 mg/kg
Result:	low acute oral toxicity in rats

9.1.2 Skin Irritation {Kreiling, 1995 #96}

Species/strain:	rabbit/New Zealand white

Number/sex of animals: 3/female

Observation period: 72 hours

Method of administration: 0.5 g of test article pasted with 0.2 ml sesame oil applied to shaved skin and semi-occluded for four hours then removed

Draize scores {Draize, 1959 #4}: low level erythema (score 1) for all animals at 24 hours

[a] see Attachment 1 for Draize scales

Test method: similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

Result: slight skin irritant in rabbits

9.1.3 Eye Irritation {Kreiling, 1995 #97}

Species/strain: rabbit/New Zealand white

Number/sex of animals: 3/female

Observation period: 72 hours

Method of administration: 100 mg of test article placed in conjunctival sac of the left eye of each rabbit

Draize scores {Draize, 1959 #4} of unirrigated eyes:

		Time after instillation					
Animal		**1 day**		**2 days**		**3 days**	
Cor	**ea**	**o[a]**	**a[b]**	**o[a]**	**a[b]**	**o[a]**	**a[b]**
	1	[1]0	0	0	0	0	0
	2	0	0	0	0	0	0
	3	0	0	0	0	0	0
Iris							
	1	0		0		0	
	2	0		0		0	
	3	0		0		0	
Con	**unctiv a**	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**
	1	2	0	0	1	0	0	0	0	0
	2	2	0	0	1	0	0	0	0	0
	3	2	0	0	1	0	0	0	0	0

[1] see Attachment 1 for Draize scales
[a] opacity [b] area [c] redness [d] chemosis [e] discharge

Test method: similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

Result: slight eye irritant in rabbits

9.4 Overall Assessment of Toxicological Data

Toxicology data for polymers of NAMW greater than 1 000 are not required according to the Act. The notifier has provided a number of toxicology reports for the technical grade of the product Dodiflow V4313-1 Conc.. The tests indicate that this is of low acute oral toxicity to rats although doses of 2 000 mg/kg did result in some clinical effects such as abnormal gait and respiration. The product was a slight eye and skin irritant in rabbits although these effects were transient and minor and were insufficient to require a hazardous classification according to the Worksafe Australia *Approved Criteria for Classifying Hazardous Substances* {National Occupational Health and Safety Commission, 1994 #9}. No test data were available to determine the genotoxic potential, sensitisation potential or subchronic toxicity of the formulation or polymer.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Although no ecotoxicological data has to be provided for polymers of NAMW > 1 000 according to the Act, the company did provide data for an acute toxicity test for fish.

The result is summarised below:

Species	Test	Result
Zebra fish *Brachydanio rerio*	Acute Toxicity	NOEC > 1 000 mg/L

The ecotoxicity data for the notified chemical indicate that the polymer is non-toxic to fish up to its solubility limit. The effect of the polymer on fish was investigated at only 1 000 mg/L (nominal concentration). This concentration is well above the solubility of the polymer, which is reflected in the fact that the tested concentration showed turbidity and substance deposits were observed on the surface of the water. No attempt was made to determine the actual concentration of the polymer in the test water.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The polymer will be used as an fuel additive and the main exposure will be from incomplete combustion or spills during handling (eg. filling tanks) and leaks from transport vehicles. Given that the polymer would be widely dispersed and would be at very low concentrations, environmental exposure would appear to be very low. Any polymer that was lost to the environment would adsorb to soils or sediments adjacent the road.

Waste polymer from reformulation will ultimately be consigned to landfill. The polymer is not expected to be mobile in landfill due to its low water solubility.

The environmental hazard from the notified polymer is rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer has a molecular weight in excess of 1 000 and is unlikely to cross biological membranes. It has a low level of low molecular weight species, less than 2% with a molecular weight of less than 1 000. The product imported for use in Australia, Dodiflow V4313, contains a high level of one of the copolymer's monomers, this is because an excess of this monomer is deliberately added when forming the copolymer. This monomer is not listed as being hazardous on the Worksafe Australia *List of Designated Hazardous Substances* {National Occupational Health and Safety Commission, 1994 #10} nor are any significant toxicological effects listed on Toxline {Toxline Silver Platter, 1996 #27}. Dodiflow V4313 is classified as a flammable liquid according to the *Australian Dangerous Goods Code* {Federal Office of Road Safety, 1992 #5} as it has a flash point below 61°C.

Specific toxicological data for the notified copolymer is not available, the notifier has however provided limited toxicity data for the technical grade of the product, Dodiflow V4313-1 Conc. This has a low acute oral toxicity in rats and is not

classified as either a skin or an eye irritant in rabbits according to the Worksafe Australia *Approved Criteria for the Classification of Hazardous Substances* {National Occupational Health and Safety Commission, 1994 #9}, the effects seen in these studies were slight and transient. The imported product, Dodiflow V4313, due to its close compositional similarity to the technical grade, would not be classified as hazardous.

The imported product, Dodiflow V4313, is mixed with other liquids to form commercial products. The notifier has indicated that these other liquids are classified as hazardous. They are blended in sufficient quantities to render the commercial products hazardous.

Occupational exposure to the notified polymer will be limited as the processes of blending and dosing of the diesel fuel occur under automated conditions with suitable ventilation to limit atmospheric exposure. The potential for exposure is greatest when handling the formulations for analytical purposes or when undertaking maintenance of equipment that comes into contact with the copolymer such as pumps and pipes. The principle exposure pathway will be dermal with the possibility of inhalational exposure. The vapour pressure of the notified copolymer is unknown however it is likely to be low on the basis of the NAMW of the copolymer, this is likely to limit inhalational exposure. The addition of relatively volatile aromatics during reformulation of the notified copolymer indicates that there will be potential for exposure to these compounds if ventilation is inadequate.

On the basis of the toxicological data provided and an evaluation of possible occupational exposure it is considered that the risk through occupational exposure to the notified copolymer is low.

Under normal conditions of transport, handling and end-use, the likelihood of public exposure to this material is very low. Dodiflow V4313 and diesel additive concentrates will not be available to the public. There may be widespread potential for public contact with diesel fuels that contain the notified chemical. However, because of the low concentration of the polymer in fuels, the potential for public exposure to the notified chemical during use of this material is minimal.

13. RECOMMENDATIONS

To minimise occupational exposure to Copolymer in Dodiflow V4313 and other components of the formulation, Dodiflow V4313 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 {Standards Australia, 1994 #21} to comply with Australian/New Zealand Standard (AS/NZS) 1337 {Standards Australia/Standards New Zealand, 1992 #23};

- Industrial clothing should conform to the specifications detailed in AS 2919 {Standards Australia, 1987 #18};

- Impermeable gloves or mittens should conform to AS 2161 {Standards Australia, 1978 #17};

- All occupational footwear should conform to AS/NZS 2210 {Standards Australia/Standards New Zealand, 1994 #24};

- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion;

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

In addition, when handling the diesel additive, which contains the notified polymer, in conditions with inadequate ventilation, it is advisable to use the appropriate respiratory device which should be selected and used in accordance to AS/NZS 1715 {Standards Australia/Standards New Zealand, 1994 #25} and should conform to AS/NZS 1716 {Standards Australia/Standards New Zealand, 1994 #26}.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* {National Occupational Health and Safety Commission, 1994 #13}.

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

1. National Occupational Health and Safety Commission 1994, *List of Designated Hazardous Substances [NOHSC:10005(1994)]*, Australian Government Publishing Service, Canberra.

2. Toxline Silver Platter 1996, *Toxline SilverPlatter CD-ROM database: January 1994-June 1996*, Silver Platter International, N.V.

3. National Occupational Health and Safety Commission 1995, 'Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment, [NOHSC:1003(1995)]', in *Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards*, Australian Government Publishing Service, Canberra.

4. Anliker, R., Moser, P. & Poppinger, D. 1988, 'Bioaccumulation of dyestuffs and organic pigments in fish. Relationships to hydrophobicity and steric factors', *Chemosphere*, vol. 17, no. 8, pp. 1631-1644.

5. Gobas, F.A.P.C., Opperhuizen, A. & Hutzinger, O. 1986, 'Bioconcentration of hydrophobic chemicals in fish: relationship with membrane permeation', *Environmental Toxicology and Chemistry*, vol. 5, pp. 637-646.

6. Hoffman, D. 1995, *Dodiflow V 4313-1 conc. Testing for Acute Oral Toxicity in the Male and female Wistar Rat*, Project no., Project No. 95.0247, Hoechst, Pharma Development, Frankfurt am Main.

7. Kreiling, D. 1995, *Dodiflow V 4313-1 conc. Test for Primary Dermal Irritation in the Rabbit*, Project no., Project number 95.0234, Hoechst, Pharma Development, Frankfurt am Main.

8. Kreiling, D. 1995, *Dodiflow V 4313-1 conc. test for Primary Eye Irritation in the Rabbit*, Project no., Project number 95.0125, Hoechst, Pharma Development, Frankfurt am Main.

9. Organisation for Economic Co-operation and Development 1995-1996, *OECD Guidelines for the Testing of Chemicals on CD-Rom*, OECD, Paris.

10. Draize, J.H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US*, vol. 49, pp. 2-56.

11. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra.

12. Federal Office of Road Safety 1992, *Australian Code for the Transport of Dangerous Goods by Road and Rail*, 5th edn, Australian Government Publishing Service, Canberra.

13. Standards Australia 1994, *Australian Standard 1336-1994, Eye protection in the Industrial Environment*, Standards Association of Australia, Sydney.

14. Standards Australia/Standards New Zealand 1992, *Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

15. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing*, Standards Association of Australia, Sydney.

16. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves)*, Standards Association of Australia, Sydney.

17. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear*, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

18. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1715-1994, Selection, Use and Maintenance of Respiratory Protective Devices*, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

19. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices*, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

20. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, Australian Government Publishing Service, Canberra.

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe