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December 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Chimassorb 2020

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Chimassorb 2020

1. APPLICANT

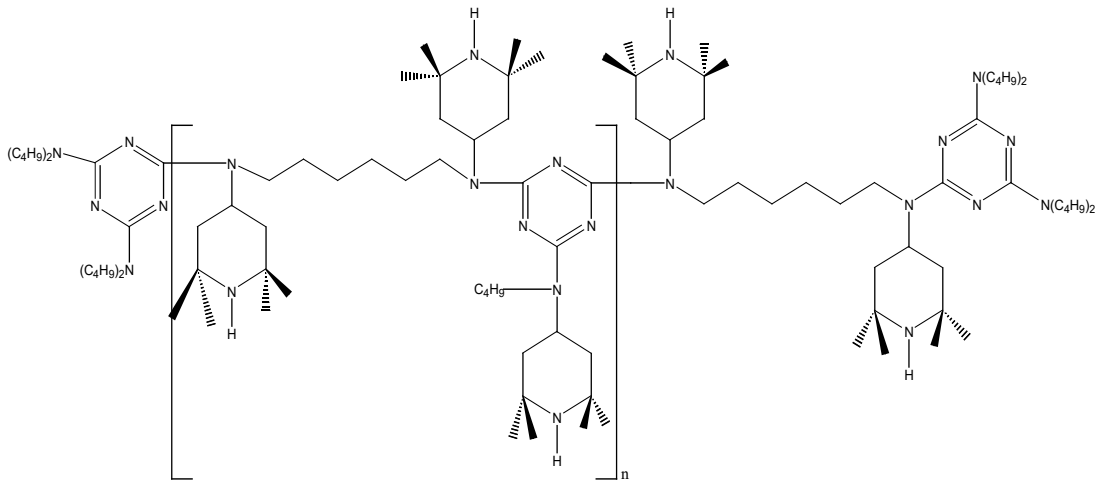
Ciba Specialty Chemicals Ltd of 235 Settlement Road THOMASTOWN VIC 3074 has submitted a limited notification statement in support of their application for an assessment certificate for Chimassorb 2020.

The notifier has not requested any information relating to the notified chemical to be exempt from publication in the Full Public Report and Summary Report.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	1,6-Hexanediamine, N,N'-bis(2,2,6,6-tetramethyl-4-piperidinyl)- polymer with 2,3,6-trichloro-1,3,5-triazine, reaction products with, N-butyl-1-butanamine and N-butyl-2,2,6,6-tetramethyl-4-piperidinamine
Chemical Abstracts Service (CAS) Registry No.:	192268-64-7
Other Names:	CGL 2020 TKA 40152
Marketing Name:	Chimassorb 2020
Molecular Formula:	$C_{19}H_{36}N_5$ $(C_{40}H_{75}N_9)_n$ $C_{43}H_{84}N_9$

Structural Formula:



Where n = 0, 2, 4, 6, 8…

Number-Average	Approximately 2 900

Molecular Weight (NAMW):

Weight-Average Molecular Weight (WAMW): Approximately 3 500 – 3 900

Polydispersity: 1.2 – 1.3

Maximum Percentage of Low Molecular Weight Species
Molecular Weight < 500: 0%
Molecular Weight < 1 000: 0%

Weight Percentage of Ingredients:

Chemical Name	*CAS No.*	*Weight %*
Dibutylamine	111-92-2	21
Cyanuric chloride	108-77-0	13
1,6-Hexanediamine, N,N'-bis (2,2,6,6-tetramethyl-4-piperidinyl)- (T5)	61260-55-7	49
4-Piperidinamine, N-butyl-2,2,6,6-tetramethyl- (T7)	36177-92-1	17

Method of Detection and Determination: Fourier Transform Infrared (FTIR) spectrophotometer, Gel Permeation Chromatography (GPC), High Performance Liquid Chromatography (HPLC) and Gas Chromatography (GC)

Spectral Data: IR spectrum peaks are 3446, 2956, 2931, 2880, 1537, 1474, 1423, 1385, 1312, 1242, 1203, 1088 and 810 cm^{-1}

Comments on Chemical Identity

The notifier has provided an infrared spectrum and a GPC trace for the chemical. A test report for the analysis of the chemical, which included gas and high performance liquid chromatography, was provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: transparent, slightly yellow pellets

Melting Point: 130-136°C

Glass Transition Temperature: 92°C

Density: 1.01 g/m^3at 22°C

Vapour Pressure:	7×10^{-13} kPa at 20°C
Water Solubility:	<0.5 mg/L (detection limit)
Partition Co-efficient (n-octanol/water):	log P_{ow} > 10; (calculated log P_{ow} = 12.4 at pH 7)
Hydrolysis as a Function of pH:	Not determined
Adsorption/Desorption:	>5.6 (see comments below)
Dissociation Constant:	Not applicable
Particle Size:	Mass median diameter = 1039µm <1% particles <100µm diameter
Flammability Limits:	Not determined, combustible
Autoignition Temperature:	Does not self-ignite
Explosive Properties:	Not explosive
Reactivity/Stability:	Stable; does not possess oxidising properties

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice.

Melting point was determined via the 92/69/EEC, A.1 guideline. Initially, differential-scanning calorimetry (DSC) was used but found to be unsuitable for the polymer. Melting point was then determine visually using a liquid bath technique and found to be between 120 and 260ºC with decomposition starting at approximately 140ºC.

The density was determined using the 92/69/EEC, A.3 guideline. A Beckman air comparison pycnometer was used with helium (>99.8%) as the test gas. It was noted that the temperature at the time of the study was 22ºC rather than 20ºC.

OECD test guideline No 104 was used to determine the vapour pressure of the polymer. However, instead of using the recommended gas saturation method for low vapour pressure range, an in-house thermobalance method was used. Benzoic acid was used to confirm the validity of this method. Three scans were done. The notified polymer has a low volatility.

The water solubility was determined using the 92/69/EEC, A.6 guideline. A preliminary visual test then a flask test were conducted. The flask contents were stirred for up to 3 days then allowed to come to equilibrium for 24 hrs. The solution was then analysed with a spectrophotometer and the solubility determined. As the water solubility is <0.5 mg/L, this

polymer would be considered as slightly soluble.

The notifier did not attempt to determine the hydrolysis or dissociation constant of the polymer due to its low water solubility. The polymer does not contain any groups that are generally accepted as likely to hydrolyse. It does contain a number of basic nitrogen that might dissociate. However, this would be slowed by the polymer's low solubility.

A partition coefficient test was conducted using the fragment method as discussed in Annex to 92/69/EEC, A.8 guideline. A preliminary study indicated that the polymer was not suitable for the measurement of the log P_{ow} via the flask shaking or HPLC methods. The fragment method is based on the formal fragmentation of a molecule into substructures which have known log P_{ow}. Where log P_{ow} for the substructures are known, the log P_{ow} for the whole polymer can be calculated by multiplying the substructure value by the number of times it occurs in the structure, and adding the values. If necessary, corrections can be made for any intramolecular interactions. A high log P_{ow}, as in this case, indicates that the polymer is very hydrophobic. This is supported by the low water solubility.

A detailed adsorption/desorption test report was provided. An HPLC-screening method was used to determine the adsorption of the notified polymer on soil. This study used log K_{oc} determined via the OECD Guideline No.106 for plot calibration. The findings of the study showed that log K_{oc} for the polymer was much greater than the highest log K_{oc} calibration available (ie for 4,4'-DDT) from the OECD Guideline, i.e. much greater than 5.6. Since this is the highest reference value available for calibration, it is not valid to extrapolate further.

4. PURITY OF THE CHEMICAL

Degree of Purity: >97%

Impurities: 2.24% (unknown component)

Maximum Content of Residual Monomers:

Chemical Name	*CAS No.*	*Weight %*
Dibutylamine	111-92-2	<0.05
1,6-Hexanediamine, N,N'-bis (2,2,6,6-tetramethyl-4-piperidinyl)- (T5)	61260-55-7	<0.05
4-Piperidinamine, N-butyl-2,2,6,6-tetramethyl- (T7)	36177-92-1	<0.05
1,3,5-Triazin-2-amine, N-butyl-4,6-dichloro-N-(2,2,6,6-tetramethyl-4-piperidinyl)- (THH7)	63812-63-5	≤0.10
N,N,N',N'-tetrabutyl-N''-(2,2,6,6-tetramethyl-piperidin-4-yl)-N''-[6(2,2,6,6-tetramethyl-piperidin-4-ylamino)-hexyl]-[1,3,5]-triazine-2,3,6-triamine (THDBA-T5)	Not assigned	ca. 0.5
N,N,N',N'-tetrabutyl-6-hydroxy-1,3,5- triazine-2,4-diamine (CB 36-017)	Not assigned	<0.5
N,N,N',N,-tetrabutyl-6-chloro-1,3,5-triazine-2,4-diamine) (CB 35-008) (THDBA)	Not assigned	<0.06

Additives/Adjuvants:

Chemical Name	*CAS No.*	*Weight %*
xylene	1330-20-7	<0.5
water	7732-18-5	0.5

5. USE, VOLUME AND FORMULATION

The notified polymer, Chimassorb 2020, will not be manufactured in Australia. It will be imported in 25 kg bags as ready to use solid pellets for formulation and subsequent use by manufacturers of fibres, tapes, films and articles. It will be used as a light and heat stabiliser additive in plastic products. It may be used in a food contact additive.

The annual import volume of the notified polymer are as follows:

Year	Chimassorb 2020 in tonnes
1	1 – 2
2	2 – 3
3	3 – 5
4	5 – 8
5	5 – 10

6. OCCUPATIONAL EXPOSURE

The notified polymer is to be imported in a pellet form. It will be compounded with other

ingredients by extrusion to produce a masterbatch containing approximately 1 to 10% notified polymer. The masterbatch, also in a pellet form, will be bagged and sold to customers for incorporation into plastic products containing approximately 0.1 to 1% notified polymer.

Storage and transport workers are unlikely to be exposed to the notified polymer unless the packaging is breached.

Formulation of masterbatch pellets

Three (3) factory sites will be producing masterbatch containing the notified polymer. Each factory site will have approximately 15 workers handling the notified polymer. At the formulation site, the operators will weigh and add the notified polymer into the hopper through a loading port on a tumble blender, where the notified polymer is mixed with other ingredients. The mix is extruded and diced to produce the masterbatch in pellet form. During the hot-melt extrusion process, the notified polymer becomes encapsulated within the polymer matrix. The plastic pellets are bagged in 25 or 500 kg packs, ready for distribution to customers.

The main exposure to the notified polymer occurs by skin contact during weighing and feeding of the pellets into the blending machine. All workers involved in the production of masterbatch will wear personal protective equipment including gloves, safety glasses and overalls. Respiratory equipment is available for use if the local exhaust ventilation is inadequate. Local exhaust ventilation is employed during weighing, dispensing, blending and packing of pellets containing the notified polymer. Similarly, the extruder loading and exit areas are fitted with local exhaust ventilation to capture fugitive emissions from the heated polymer.

Manufacture of plastic products

Up to nine (9) plastic manufacturers are expected to be involved in using the masterbatch. Two (2) workers in each manufacturing site will handle the masterbatch. The masterbatch will be added and mixed with other ingredients into the hopper of a heat-moulding machine. Once heated the polymer melt is injected into a mould to form the shape of the plastic article required.

Since the notified polymer is encapsulated in the compounded plastic pellets, worker exposure to the notified polymer *per se* during incorporation with plastic products is not possible. During these activities, workers are required to wear gloves and eye protection. Local exhaust ventilation is in place, and would capture any fugitive emissions from the notified polymer when heated.

7. PUBLIC EXPOSURE

The preparation of plastic masterbatches is a controlled process. Weighing and blending operations are carried out with local exhaust ventilation to capture fugitive dusts. Empty containers will be purged before disposal. Up to 0.62% of the notified polymer is expected to be generated as waste during resin processing operations, and will be disposed of to landfill or by incineration. The notified polymer will be used as a minor component of plastic articles of a commercial and engineering type. The notified polymer will be encapsulated within the plastic articles and is not expected to leach from the plastic products. Contact with the notified polymer by members of the public is expected to be negligible.

8. ENVIRONMENTAL EXPOSURE

Release

During the production of masterbatch formulations the possible sources of waste include spills, bag residue and equipment cleaning. Presumably any spills will be collected and fed into the process if not contaminated. Process equipment is purged with parent polymer and then the material is recycled back into the process. No waste will enter the sewer from the masterbatch formulation plants.

The notifier has stated that the residue in the import packaging 'is expected to be very small as there is no powder to cling to the walls'. However, no quantification or estimation as to percentage residue has not been provided. Due to the nature of the material, the percentage residue would be expected to be less than 0.5% (ie a maximum of about 50 kg in year 5). Presumably these bags will end up in a landfill.

The notifier has estimated that up to 0.62% loss will occur at resin processing plants, ie in year 5 up to 62 kg of waste will be generated. This includes bag residue, offcuts and any other machining that may occur. This material will be recycled, if possible, or go to landfill.

Fate

The majority of waste generated will be recycled with some going to landfill.

Once the masterbatch has been processed the notified polymer will be bound in a stable matrix. The polymer will not leach out of the product. Any masterbatch material disposed of to landfill will not leach out due to the low solubility of the polymer and would be expected to slowly degrade.

While a polymer/chemical with a log P_{ow} >3 has the potential to bioaccumulate, this effect is inhibited or prevented by the following factors:

- a molecular weight > 1000,
- a calculated least molecular diameter of >5.5 Å, or
- molecular length > 5.5 nm (OECD, 1995).

Since this polymer is likely to satisfy all of these criteria it is unlikely that it will bioaccumulate despite having a high log P_{ow}.

9. EVALUATION OF TOXICOLOGICAL DATA

In support of their application for an assessment certificate the notifier provided the following toxicity studies using Chimassorb 2020.

9.1 Acute Toxicity

Summary of the acute toxicity of Chimassorb 2020

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	Rat	LD_{50} > 2000 mg/kg	(Busschers, 1997)
eye irritation	Rabbit	non-irritating	(Braun, 1997)
skin sensitisation	Guinea pig	non-sensitising	(Pels Rijcken, 1996)

9.1.1 Oral Toxicity (Busschers, 1997)

Species/strain:	rat/Wistar
Number/sex of animals:	3/sex
Observation period:	15 days
Method of administration:	oral gavage; 2000 mg/kg
Test method:	OECD TG 423
Mortality:	no mortality occurred during the observation period
Clinical observations:	no clinical signs observed during the observation period
Morphological findings:	no abnormalities found at post mortem examination
LD_{50}:	> 2000 mg/kg
Result:	the notified polymer was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity

A dermal toxicity study was not provided for the notified polymer.

9.1.3 Inhalation Toxicity

An inhalation toxicity study was not provided for the notified polymer.

9.1.4 Skin Irritation

A skin irritation study was not provided for the notified polymer.

9.1.5 Eye Irritation (Braun, 1997)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 1 male; 2 females

Observation period: 3 days

Method of administration: Approximately 0.1 g of solid notified polymer was applied undiluted to the conjunctival sac of the left eye; the right eye served as control.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation							
Animal	***1 hour***		***1 day***		***2 days***		***3 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***
Male	[1]0	0	0	0	0	0	0	0
Female 1	0	0	0	0	0	0	0	0
Female 2	0	0	0	0	0	0	0	0
Iris								
Male	0		0		0		0	
Female 1	0		0		0		0	
Female 2	0		0		0		0	
Conjunctiva	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***
Male	1	1	0	0	0	0	0	0
Female 1	1	1	0	0	0	0	0	0
Female 2	1	1	1	0	0	0	0	0

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge

Irrigated eyes: Not performed

Comment: no clinical signs of toxicity and no deaths occurred during the observation period

the notified polymer induced a primary irritation score of 0.11; there was slight swelling and slight reddening of the conjunctiva in all animals after 1 hour; the latter finding

	persisted in one animal up to 24 hours; after 48 hours, all animals were free of findings
Result:	the notified polymer was non-irritating to the eyes of rabbits

9.1.6 Skin Sensitisation (Pels Rijcken, 1996)

Species/strain:	guinea pig
Number of animals:	7 test animals, 3 controls
Induction procedure:	only a summary report with minimum details was provided intradermal injections groups received: 1:1 mixture of FCA and water for injection, 0.5% test material in vehicle (CMC), 1:1 mixture of FCA and 1% test material or CMC topical: 7 test animals were dermally exposed to 50% test material, while the 3 controls were similarly treated, but with 1% CMC only
Challenge procedure	two weeks after the epidermal application all animals were challenged with a 50% notified polymer concentration and 1% CMC challenge reactions were assessed 24 and 48 hours after bandage removal
Test method:	not stated
Comment:	body weights and bodyweight gain of experimental and test animals were similar over the study period; there was no evidence that the notified polymer caused skin hypersensitivity in any of the guinea pigs used in the study
Result:	the notified polymer was non-sensitising to the skin of guinea pigs

9.2 Repeated Dose Toxicity

A repeated dose toxicity study was not provided for the notified polymer.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Verspeek-Rip, 1997b)

Strains:	*Salmonella typhimurium:* TA1535, TA1537, TA100, TA98 *Escherichia coli*: WP_2uvrA
Concentration range:	0, 3, 10, 33, 100, 167 μg/plate
Metabolic activation:	10% rat liver S9 fraction (Aroclor 1254-induced) with standard cofactors
Test method:	OECD TG 471/472
Positive controls	without metabolic activation: TA1535, sodium azide 1 μg/plate in saline TA1537, 9-aminoacridine 60 μg/plate in saline TA98, daunomycin 4 μg/plate in saline TA100, methylmethanesulfonate 650 μg/plate in dimethylsulphoxide (DMSO) WP_2*uvr*A, 4-nitroquinoline-N-oxide 10 μg/plate in DMSO with metabolic activation: WP_2uvrA, 2-aminoanthracene 5 μg/plate in DMSO TA1537, 2-aminoanthracene 2.5 μg/plate in DMSO TA1535, TA98 and TA100, 1-aminoanthracene 5 μg/plate in DMSO
Comment:	the notified polymer was incorporated in the assay as an ultrasonicated homogeneous suspension in ethanol dose range finding established a maximum test concentration of 167 μg/plate; even at this concentration, adverse effects were noted with the bacterial lawn, and these effects increased in severity with higher concentrations; precipitation was noted at 1000 μg/plate and upwards both negative and strain-specific-positive controls functioned within expected limits
Result:	there were no dose-related increases in numbers of revertants in two independent experiments, in the presence and absence of metabolic activation the test material was considered to be non-mutagenic under the conditions of the assay

9.3.2 *In Vitro* Mammalian Cell Gene Mutation Test (HPRT) with V79 Chinese Hamster Cells (Verspeek-Rip, 1997a)

Cells:	V79 Chinese hamster cells
Metabolic activation:	10% rat liver S9 fraction (Aroclor 1254-induced) with standard cofactors
Experimental design:	the notified polymer was dissolved in ethanol and tested in two independent experiments, in the presence and absence of metabolic activation

<u>experiment 1:</u>
without S9-mix: 0.3, 1, 3.3, 5.6 and 7.5 µg/mL
with S9-mix: 5.6, 10, 33 and 56 µg/mL

<u>experiment 2:</u>
without S9-mix: 0.3, 1, 3.3 and 5.6 µg/mL
with S9-mix: 10, 33, 56 and 100 µg/mL

negative control, vehicle (absolute ethanol)

positive control,
with S9-mix, 8 mM (final) dimethylnitrosamine (DMN) in DMSO
without S9-mix, 6 mM (final) ethylmethanesulfonate (EMS) in DMSO

<u>cell cleansing</u>
about 4-5 days before testing commenced, V79 cells were grown in HAT medium (10^{-4} M hypoxanthine, 10^{-5} M aminopterin and $1.6x10^{-5}$ thymidine in F10 culture medium) to reduce the number of spontaneous mutants in the clone

<u>cell treatment</u>
adequate numbers of cells ($2.1x10^6$ and $0.6x10^6$ per dish in experiment 1 and 2, respectively) for each respective dose (including positive and vehicle controls) were treated for 4 hours before washing to remove test material; a subfraction of 200 cells were seeded and incubated for 7 days to determine the cloning efficiency after treatment

<u>expression period</u>
remaining cells were subcultured and maintained in logarithmic growth for 7 days for expression of the mutant phenotype

<u>determination of mutant frequency</u>
a total of 10^6 cells for each dose were seeded (10^5 cells/9 cm dish) for mutant expression in selective medium (F10 culture medium containing 5 µg/mL 6-thioguanine); another subfraction of 200 cells were separately plated for cloning

	efficiency 7 days post expression period; all cells were further incubated for 7 days; in all cases, colonies were fixed with methanol, stained and counted; mutant frequencies were expressed as number of mutants per 10^5 surviving cells
Test method:	OECD TG 476
Comment:	the spontaneous mutant frequencies in the solvent-treated controls were in the expected range in the two independent experiments, the test material did not induce a significant increase in the mutant frequency, compared with solvent-treated control cultures
Result:	the notified polymer was considered to be non-mutagenic at the HPRT locus in V79 Chinese hamster cells

9.3.3 Chromosome Aberration Assay in Human Peripheral Lymphocytes (Bertens, 1997)

Cells:	Lymphocytes from healthy adult male volunteers
Metabolic activation:	1.8% (v/v, final) rat liver S9 fraction (Aroclor 1254-induced) with standard cofactors
Experimental design:	the notified polymer was dissolved in DMSO and ultrasonicated to produce a fine suspension; the final concentration of vehicle in the culture medium was 0.9%. two independent experiments, both in the presence and absence of metabolic activation, were conducted test doses were 1, 3, 10, 33, and 100 μg/mL, with and without S9-mix negative control vehicle: DMSO positive controls: with S9-mix, cyclophosphamide (CP) in Hank's Balanced Salt Solution (HBSS) at a final concentration of 15 μg/mL for a 3 hour treatment and 24 hour harvest without S9-mix, mitomycin C (MMC-C) in HBSS at a final concentration of 0.5 μg/mL for a 3 hour treatment period, 0.2 μg/ml for a 24 hour treatment period and 0.1 μg/mL for a 48 hour treatment period various combinations of treatment and harvest times were as follows:

	<u>experiment 1</u> without S9: - 3 hour treatment, 24 hour harvest - 24 hour treatment, 24 hour harvest - 48 hour treatment, 48 hour harvest with S9: - 3 hour treatment, 24 hour harvest - 3 hour treatment, 48 hour harvest <u>experiment 2</u> without S9: - 24 hour treatment, 24 hour harvest - 3 hour treatment, 24 hour harvest
Test method:	OECD TG 473
Comment:	the notified polymer did not induce any significant increase in numbers of cells with chromosome aberrations in the presence and absence of metabolic activation; positive controls, CP and MMC-C, both induced statistically significant increases in chromosome aberrations compared with vehicle controls
Result:	the notified polymer was considered to be not clastogenic in human blood peripheral lymphocytes, under the conditions described in the report

9.4 Overall Assessment of Toxicological Data

The notified polymer, Chimassorb 2020, had very low oral toxicity in the rat, with an LD_{50} > 2000 mg/kg. It was not irritating to the eyes of rabbits, nor did it sensitise the skin of guinea pigs in a maximisation test.

It was negative in bacterial mutagenicity assays with *Salmonella typhimurium* and *Escherichia coli*. In other *in vitro* genotoxicity tests, no increased mutations at the HPRT locus of V70 Chinese hamster cells were observed, and no increased chromosomal aberrations were seen in human blood peripheral lymphocytes.
Based on the data provided, Chimassorb 2020 is not considered to be a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) and will not require labelling with specific risk phrases.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided for the notified polymer.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

If the notified polymer is used in the way described by the notified it is expected to pose a

low hazard to the environment.

During the production of masterbatch formulations the possible sources of waste include spills, bag residue and equipment cleaning. Majority of waste material will be recycled with no waste entering the sewer from the masterbatch formulation plants. The notifier has not given an estimate of bag residues, but due to the nature of the material, it would be expected to be less than 0.5% (ie a maximum of about 50 kg in year 5). Presumably these bags will end up in a landfill.

The notifier has estimated that up to 0.62% loss will occur at resin processing plants, ie in year 5 up to 62 kg of waste will be generated. This includes bag residue, offcuts and any other machining that may occur. This material will be recycled, if possible, or go to landfill.

Once the masterbatch has been processed the notified polymer will be bound in a stable matrix and will not leach out. Any masterbatch material disposed of to landfill will not leach out due to the low solubility of the polymer but will very slowly degrade and not bioaccumulate. While the polymer does contain nitrogen, which can potentially be charged and therefore toxic, exposure to the aquatic compartment is very low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer, Chimassorb 2020, will be imported polymer as a free flowing pellets having a mean diameter of 1 mm, with <1% inspirable particles. The notifier provided information which states that free flowing pellets are dust free and are highly resistant to attrition. The polymer will be mixed and extruded with other ingredients to give a masterbatch suitable for use in plastic manufacture. During further processing into finished articles, the notified polymer is bound within a polymer (plastic) matrix.

The notifier provided a number of toxicological studies in support of this application. The notified polymer exhibited very low oral toxicity in the rat, with an LD_{50} > 2000 mg/kg. It was not irritating to the eyes of rabbits, nor did it sensitise the skin of guinea pigs in a maximisation test. It was negative in bacterial mutagenicity assays with *Salmonella typhimurium* and *Escherichia coli*. In other *in vitro* genotoxicity tests, no increased mutations at the HPRT locus of V70 Chinese hamster cells were observed, and no increased chromosomal aberrations were seen in human blood peripheral lymphocytes.

Based on the data provided, Chimassorb 2020, is not considered to be a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) and will not require labeling with specific risk phrases.

Occupational Health and Safety

There is potential for dermal exposure when handling the notified chemical. The potential for inhalation and eye exposure is low because the notified chemical is presented in solid pellet form designed to be anti-dusting. Under normal working conditions, storage and transport workers will be handling sealed packages of products containing the notified chemical. There are no occupational health risks for these workers.

During masterbatch production, operators weighing and adding the pellets containing the notified polymer to containers in preparation for mixing and extrusion may experience dermal exposure to the notified chemical. Since the extrusion process is enclosed, further exposure will not occur. Workers involved in the processes such as extrusion and bagging of plastic pellets would have low exposure since after compounding in the extruder, the notified chemical is encapsulated in the masterbatch pellets. The imported polymer and the masterbatch pellets which contain up to 10% polymer, are described as anti-dusting and should minimise worker exposure to chemical dust. Respiratory protection beyond the local exhaust ventilation in the weighing, extruder loading and exit area, is not needed. The notifier states that workers involved in the production of the masterbatch pellets will wear gloves, safety glasses and overalls. Use of this equipment and the low toxicity of the polymer means that the health risk to workers is low.

At the customer site, the masterbatch pellets will be mixed with other ingredients and processed to form plastic end use articles. Since the notified chemical is encapsulated within the polymer matrix in masterbatch, occupational exposure to the notified chemical cannot occur before or after the articles are made.

Public Health

The notified polymer will be encapsulated in plastics used to manufacture plastic articles for industrial and engineering use, which are unlikely to be handled by the public. The potential for public exposure to the notified polymer during transport, manufacture, in end-use products or from disposal is assessed as negligible. Based on the low potential for exposure and its low toxicity, it is considered that the notified polymer will not pose a significant hazard to human health.

13. RECOMMENDATIONS

To minimise occupational exposure to Chimmasorb 2020 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) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990); and impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia, 1998);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should 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.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994).

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 may be required if any of the circumstances stipulated under section 64 of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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

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Verspeek-Rip C (1997a) Evaluation of the Mutagenic Activity of TKA 40152 (CB 35-119) in an *In Vitro* Mammalian Cell Gene Mutation Test with V79 Chinese Hamster Cells, Project No. 209339, NOTOX B.V., The Netherlands.

Verspeek-Rip C (1997b) Evaluation of the Mutagenic Activity of TKA 40152 (CB 35-119) in *Salmonella typhimurium* Reverse Mutation Assay and the *Escherichia coli* Reverse Mutation Assay, Project No. 209328, NOTOX B.V., The Netherlands.

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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	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