Commission Regulation (EU) 2020/878



Clanobutin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
1.14	28.09.2024	3679323-00015	Date of first issue: 09.11.2018

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier		
	Trade name	:	Clanobutin Formulation
12	Relevant identified uses of th	10 5	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture		Veterinary product
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	MSD Kilsheelan Clonmel Tipperary, IE
	Telephone	:	353-51-601000
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) N	lo 1272/2008)
Skin irritation, Category 2	H315: Causes skin irritation.
Eye irritation, Category 2	H319: Causes serious eye irritation.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

Signal word	:	Warning
Hazard statements	:	H315 H319

Causes skin irritation. Causes serious eye irritation.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Preca	utionary statements	P280 We	ash skin thoroughly after handling. ear protective gloves/ eye protection/ face pro- ction.
		Response:	
			If skin irritation occurs: Get medical advice/ ention.
			If eye irritation persists: Get medical advice/ ention.
			Take off contaminated clothing and wash it fore reuse.

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 10.64 %

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Clanobutin	30544-61-7	Skin Irrit. 2; H315	>= 10 - < 20
	250-232-3	Eye Irrit. 2; H319	
		STOT SE 3; H335	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

: In the case of accident or if you feel unwell, seek medical advice immediately.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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			When symptoms advice.	persist or in all cases of doubt seek medical
Prote	ection of first-aiders	:	and use the reco	lers should pay attention to self-protection, mmended personal protective equipment al for exposure exists (see section 8).
lf inh	aled	:	If inhaled, remov Get medical atte	e to fresh air. ntion if symptoms occur.
In ca	se of skin contact	:	for at least 15 mi and shoes. Get medical atte Wash clothing be	
In ca	se of eye contact	:	for at least 15 mi	nove contact lens, if worn.
lf swa	allowed	:	Get medical atte	NOT induce vomiting. ntion if symptoms occur. roughly with water.
4.2 Most i	important symptoms a	nd e	effects, both acut	e and delayed
Risks		:	Causes skin irrita Causes serious e	ation.
4 3 Indica	tion of any immediate	mo	dical attention an	d special treatment needed
	ment	:		ically and supportively.
SECTIO	N 5: Firefighting mea	sur	es	
5.1 Exting	guishing media			
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical	
Unsu medi	itable extinguishing a	:	None known.	
5.2 Speci	al hazards arising from	the	e substance or m	ixture
-	ific hazards during fire-	:	Vapours may for	m explosive mixtures with air. bustion products may be a hazard to health.
Haza	rdous combustion prod-	:	Carbon oxides	



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ucts			Nitrogen oxides (NOx)
Specia for fire	3 Advice for firefighters Special protective equipment : for firefighters Specific extinguishing meth- ods		Use personal pro Use extinguishing cumstances and Use water spray	e, wear self-contained breathing apparatus. tective equipment. g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment.
		Follow safe handling advice (see section 7) and personal pro-
		tective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
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6.3 Methods and material for containment and cleaning up

Methods for cleaning up	 Soak up with inert absorbent material. For large spills, provide dyking or other appropriate contair ment to keep material from spreading. If dyked material ca be pumped, store recovered material in appropriate contain Clean up remaining materials from spill with suitable absor bent. Local or national regulations may apply to releases and dis 	n ner. -
	posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to dete mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regard certain local or national requirements.	r-

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Loca Advi	nical measures I/Total ventilation ce on safe handling ene measures	 CONTROLS/ Use only with Do not get or Avoid inhalat Do not swall Do not get in Wash skin th Handle in accorrection practice, basis sessment Take care to environment. If exposure to flushing system place. When nated clothing The effective engineering of appropriate of industrial hyg 	
7.2 Cond	itions for safe storage	, including any inc	compatibilities
Requ	uirements for storage	: Keep in prop	erly labelled containers. Store in accordance with

:	Keep in properly labelled containers. Store in accordance with the particular national regulations.
:	Do not store with the following product types: Strong oxidizing agents Gases
:	No data available
	:

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Clanobutin	30544-61-7	TWA	0.3 mg/m3 (OEB 2)	Internal

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.



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Laboratory operations do not require special containment.

Personal protective equipr	nt	
Eye/face protection	 Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conc mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there potential for direct contact to the face with dusts, mists aerosols. 	is a
Hand protection		
Material	: Chemical-resistant gloves	
Skin and body protection	: Work uniform or laboratory coat.	
Respiratory protection	If adequate local exhaust ventilation is not available of sure assessment demonstrates exposures outside the ommended guidelines, use respiratory protection. Equipment should conform to LS. EN 143	
Filter type	: Particulates type (P)	
Material Skin and body protection Respiratory protection	 Wear a faceshield or other full face protection if there potential for direct contact to the face with dusts, mists aerosols. Chemical-resistant gloves Work uniform or laboratory coat. If adequate local exhaust ventilation is not available or sure assessment demonstrates exposures outside the ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143 	s, or r expo-

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	93.4 °C
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available



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	рН		:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	No data available	9
	Solubil Wat	ity(ies) ter solubility	:	soluble	
	Solu	ubility in other solvents	:	No data available	
	Partitio octano	n coefficient: n- l/water	:	Not applicable	
	Vapour	pressure	:	No data available	9
	Relativ	e density	:	No data available	9
	Density	/	:	No data available	9
	Relativ	e vapour density	:	No data available	9
		e characteristics ticle size	:	Not applicable	
9.2	Other ir Explosi	nformation ives	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Evapor	ation rate	:	No data available	9
	Molecu	lar weight	:	No data available	

SECTION 10: Stability and reactivity

10.1 Reactivity Not classified as a reactivity haza	ırd.
10.2 Chemical stability	
Stable under normal conditions.	
10.3 Possibility of hazardous reaction	ons
Hazardous reactions :	Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
10.4 Conditions to avoid	
Conditions to avoid :	None known.
10.5 Incompatible materials	
Materials to avoid :	Oxidizing agents
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according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Clanobutin:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Rat): 570 mg/kg Application Route: Intravenous

Skin corrosion/irritation

Causes skin irritation.

Components:

Clanobutin:

Result :

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Clanobutin:

Result

: Severe irritation

irritating

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

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Reproductive toxicity

Not classified based on available information.

Components:

Clanobutin:

Effects on foetal develop- ment	:	Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 250 mg/kg body weight
		Test Type: Development

Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 250 mg/kg body weight

STOT - single exposure

Not classified based on available information.

Components:

Clanobutin:

Exposure routes	:	Inhalation
Assessment	:	May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Clanobutin:

Species LOAEL Application Route Exposure time Target Organs Symptoms	:	Dog 500 mg/kg Oral 4 Weeks Central nervous system Tremors, Disorientation
Species NOAEL LOAEL Application Route Exposure time Target Organs	:	Rat 300 mg/kg 500 mg/kg Oral 6 Months Kidney, Liver, Thyroid
Species NOAEL LOAEL Application Route Exposure time Target Organs	: : : : : : : : : : : : : : : : : : : :	Dog 300 mg/kg 600 mg/kg Oral 6 Months Kidney, Liver, Thyroid

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Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Clanobutin:

Ecotoxicology Assessment

Acute aquatic toxicity	:	Toxic effects cannot be excluded
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Chronic aquatic toxicity : Toxic effects cannot be excluded

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment	: The substance/mixture does not contain components consid-
	ered to have endocrine disrupting properties according to
	REACH Article 57(f) or Commission Delegated regulation



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(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.3 Transport hazard class(es)		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
11 1 Decking group		

14.4 Packing group

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

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ADN		: Not regulated as a dangerous good		
ADR		: Not regulated as a dangerous good		
RID		: Not regulated as a dangerous good		
IMDG	i	: Not regulated as a dangerous good		
ΙΑΤΑ	(Cargo)	: Not regulated as a dangerous good		
ΙΑΤΑ	(Passenger)	: Not regulated as a dangerous good		
14.5 Envir	onmental hazards			
Not regulated as a dangerous good				
14.6 Spec	ial precautions for us	er		
NI-C-	N la Cara d'Arab la			

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing of the market and use of certain dangerous substance mixtures and articles (Annex XVII)	
	Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the condi- tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not.
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	
Regulation (EC) on substances that deplete the ozo layer	ne : Not applicable
Regulation (EU) 2019/1021 on persistent organic potants (recast)	llu- : Not applicable
Regulation (EU) No 649/2012 of the European Parli ment and the Council concerning the export and imp of dangerous chemicals	
REACH - List of substances subject to authorisation (Annex XIV)	: Not applicable
Seveso III: Directive 2012/18/EU of the European P major-accident hazards involving dangerous substa Not applicable	



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The c AICS	components of this p	roduct are reported : not determine	l in the following inventories:	
DSL		: not determine	d	
IECS	С	: not determine	d	
15.2 Chemical safety assessment				

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
Full text of H-Statements		
H315	:	Causes skin irritation.
H319	:	Causes serious eye irritation.
H335	:	May cause respiratory irritation.
Full text of other abbreviati	ons	
Eye Irrit.	:	Eye irritation
Skin Irrit.	:	Skin irritation

Skin Irrit.:Skin irritationSTOT SE:Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response: GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European



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Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:	Classification procedure:	
Sources of key data used to	Internal technical data, data from raw material SDSs, OEC	
compile the Safety Data	eChem Portal search results and European Chemicals Age	
Sheet	cy, http://echa.europa.eu/	

Classification of the mixture:		Classification procedu	
Skin Irrit. 2	H315	Calculation method	
Eye Irrit. 2	H319	Calculation method	

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IE / EN