SAFETY DATA SHEET

According to 1907/2006/EC, Article 31

	Revision number: 1	Revision date: 04/09/2019
SECTION 1: Identification of the	e substance/mixture and of the company/undertaking	
1.1 Product identifiers		
Product name:	Ramelteon	
Product code:	R0216	
1.2 Relevant identified uses of the s Identified uses:	substance or mixture and uses advised against Reagents.	
1.3 Details of the supplier of the sat Supplier:	fety data sheet	
TCI EUROPE N.V.		
Boerenveldseweg 6		
Haven 1063		
B-2070 Zwijndrecht		
Telephone: +32(0)3 735 07		
E-mail: sales-eu@tcichemi	cals.com	
I.4 Emergency telephone number:	+32(0)70 245 245	
SECTION 2: Hazards identificat		
2.1 Classification of the substance		
Acute toxicity (Oral)	Category 4	
Reproductive toxicity 2.2 Label elements Pictograms or hazard symbols	Category 2	
2.2 Label elements Pictograms or hazard symbols		
2.2 Label elements	Warning	
2.2 Label elements Pictograms or hazard symbols	Warning H302-Harmful if swallowed.	soro obild
2.2 Label elements Pictograms or hazard symbols Office of the symbols Signal word Hazard statements	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb	born child.
2.2 Label elements Pictograms or hazard symbols	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use.	oorn child.
2.2 Label elements Pictograms or hazard symbols Office of the symbols Signal word Hazard statements	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product.	oorn child.
2.2 Label elements Pictograms or hazard symbols Office of the symbols Signal word Hazard statements	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product. P264-Wash hands and face thoroughly after handling.	oorn child.
2.2 Label elements Pictograms or hazard symbols Signal word Hazard statements	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product.	oorn child.
2.2 Label elements Pictograms or hazard symbols Signal word Hazard statements	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product. P264-Wash hands and face thoroughly after handling. P280-Wear protective gloves, protective clothing, face protection.	oorn child.
2.2 Label elements Pictograms or hazard symbols Of the symbols Signal word Hazard statements Precautionary statements	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product. P264-Wash hands and face thoroughly after handling. P280-Wear protective gloves, protective clothing, face protection. P308+P313-IF exposed or concerned: Get medical advice or attention. P405-Store locked up.	oorn child.
2.2 Label elements Pictograms or hazard symbols Signal word Hazard statements	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product. P264-Wash hands and face thoroughly after handling. P280-Wear protective gloves, protective clothing, face protection. P308+P313-IF exposed or concerned: Get medical advice or attention. P405-Store locked up.	oorn child.
2.2 Label elements Pictograms or hazard symbols Signal word Hazard statements Precautionary statements 2.3 Other hazards	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product. P264-Wash hands and face thoroughly after handling. P280-Wear protective gloves, protective clothing, face protection. P308+P313-IF exposed or concerned: Get medical advice or attention. P405-Store locked up.	oorn child.
2.2 Label elements Pictograms or hazard symbols Signal word Hazard statements Precautionary statements 2.3 Other hazards Results of PBT and vPvB assess	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product. P264-Wash hands and face thoroughly after handling. P280-Wear protective gloves, protective clothing, face protection. P308+P313-IF exposed or concerned: Get medical advice or attention. P405-Store locked up.	oorn child.
2.2 Label elements Pictograms or hazard symbols Signal word Hazard statements Precautionary statements 2.3 Other hazards Results of PBT and vPvB assess PBT: vPvB:	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product. P264-Wash hands and face thoroughly after handling. P280-Wear protective gloves, protective clothing, face protection. P308+P313-IF exposed or concerned: Get medical advice or attention. P405-Store locked up. ment Not applicable Not applicable	oorn child.
2.2 Label elements Pictograms or hazard symbols Signal word Hazard statements Precautionary statements 2.3 Other hazards Results of PBT and vPvB assess PBT: vPvB: SECTION 3: Composition/inform 3.1 Substances	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product. P264-Wash hands and face thoroughly after handling. P280-Wear protective gloves, protective clothing, face protection. P308+P313-IF exposed or concerned: Get medical advice or attention. P405-Store locked up. ment Not applicable Not applicable mation on ingredients	oorn child.
2.2 Label elements Pictograms or hazard symbols Signal word Hazard statements Precautionary statements 2.3 Other hazards Results of PBT and vPvB assess PBT: vPvB: SECTION 3: Composition/inform 3.1 Substances Components:	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product. P264-Wash hands and face thoroughly after handling. P280-Wear protective gloves, protective clothing, face protection. P308+P313-IF exposed or concerned: Get medical advice or attention. P405-Store locked up. ment Not applicable Not applicable mation on ingredients Ramelteon	oorn child.
2.2 Label elements Pictograms or hazard symbols Signal word Hazard statements Precautionary statements 2.3 Other hazards Results of PBT and vPvB assess PBT: vPvB: <u>SECTION 3: Composition/inform</u> 3.1 Substances Components: Percent:	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product. P264-Wash hands and face thoroughly after handling. P280-Wear protective gloves, protective clothing, face protection. P308+P313-IF exposed or concerned: Get medical advice or attention. P405-Store locked up. ment Not applicable Not applicable mation on ingredients Ramelteon >98.0%(GC)	oorn child.
2.2 Label elements Pictograms or hazard symbols Signal word Hazard statements Precautionary statements 2.3 Other hazards Results of PBT and vPvB assess PBT: vPvB: SECTION 3: Composition/inform 3.1 Substances Components:	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product. P264-Wash hands and face thoroughly after handling. P280-Wear protective gloves, protective clothing, face protection. P308+P313-IF exposed or concerned: Get medical advice or attention. P405-Store locked up. ment Not applicable Not applicable mation on ingredients Ramelteon	oorn child.
2.2 Label elements Pictograms or hazard symbols Signal word Hazard statements Precautionary statements 2.3 Other hazards Results of PBT and vPvB assess PBT: vPvB: <u>SECTION 3: Composition/inform</u> 3.1 Substances Components: Percent:	Warning H302-Harmful if swallowed. H361fd-Suspected of damaging fertility. Suspected of damaging the unb P201-Obtain special instructions before use. P270-Do not eat, drink or smoke when using this product. P264-Wash hands and face thoroughly after handling. P280-Wear protective gloves, protective clothing, face protection. P308+P313-IF exposed or concerned: Get medical advice or attention. P405-Store locked up. ment Not applicable Not applicable mation on ingredients Ramelteon >98.0%(GC)	

G

TCI EUROPE N.V.

SECTION 4: First aid measures	
4.1 Description of first aid measure	S
Inhalation:	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention.
Skin contact:	Remove/Take off immediately all contaminated clothing. Gently wash with plenty of soap and water. Get medical advice/attention.
Eye contact:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Get medical advice/attention.
Ingestion:	Get medical advice/attention.Rinse mouth.
Protection of first-aiders:	A rescuer should wear personal protective equipment, such as rubber gloves and air-tight goggles.

^{4.2} Most important symptoms and effects, both acute and delayed No data available

4.3 Indication of any immediate medical attention and special treatment needed No data available

SECTION 5: Firefighting measures		
5.1 Extinguishing media		
Suitable extinguishing media:	Dry chemical, foam, water spray, carbon dioxide.	
5.2 Special hazards arising from the substance or mixture	Take care as it may decompose upon combustion or in high temperatures to generate poisonous fume. Carbon dioxide, Carbon monoxide, Nitrogen oxides (NOx)	
5.3 Advice for firefighters	Fire-extinguishing work is done from the windward and the suitable fire-extinguishing method according to the surrounding situation is used. Uninvolved persons should evacuate to a safe place. In case of fire in the surroundings: Remove movable containers if safe to do so. When extinguishing fire, be sure to wear personal protective equipment	
SECTION 6: Accidental release mea	asures	
6.1 Personal precautions, protective equipment and emergency procedures	Use personal protective equipment. Keep people away from and upwind of spill/leak. Entry to non-involved personnel should be controlled around the leakage area by roping off, etc	
6.2 Environmental precautions	Prevent product from entering drains	
6.3 Methods and materials for containment and cleaning up	Sweep dust to collect it into an airtight container, taking care not to disperse it. Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.	
6.4 Reference to other sections	For disposal see section 13.	
SECTION 7: Handling and storage		
7.1 Precautions for safe handling	Handling is performed in a well ventilated place. Wear suitable protective equipment. Prevent dispersion of dust. Wash hands and face thoroughly after handling. Use a closed system if possible. Use a local exhaust if dust or aerosol will be generated. Avoid all contact!	
7.2 Conditions for safe storage, including any incompatibilities	Keep container tightly closed. Store in a cool and dark place. Store locked up. Store away from incompatible materials such as oxidizing agents.	
7.3 Specific end use(s)	No further relevant information available.	
SECTION 8: Exposure controls/per	sonal protection	
8.1 Control parameters	No data available	
8.2 Exposure controls	Install a closed system or local exhaust. Also install safety shower and eye bath.	
Respiratory protection: Hand protection:	Dust respirator, self-contained breathing apparatus(SCBA), supplied air respirator, etc. Use respirators approved under appropriate government standards and follow local and national regulations. Impervious gloves.	
Eye protection: Skin and body protection:	Safety goggles. A face-shield, if the situation requires. Impervious protective clothing. Protective boots, if the situation requires.	

SECTION 9: Physical and chemical properties			
9.1 Information on basic physical and chemical properties			
Physical state (20°C):	Solid		
Form:	Crystal - Powder		
Colour:	White - Very pale yellow		
Odour:	No data available		
pH:	No data available		
Melting point/freezing point:	116°C		
Boiling point/range:	No data available		
Flash point:	No data available		
Evaporation rate(Butyl Acetate=1):	No data available		
Flammability(solid, gas):	No data available		
Flammability or explosive limits:			
Lower:	No data available		
Upper:	No data available		
Vapour pressure:	9.9 x 10 [.] kPa/25°C		
Vapour density:	No data available		
Relative density:	No data available		
Solubility(ies):			
[Water]	Insoluble (11mg/L, 25°C)		
[Other solvents]			
Soluble:	Ethanol		
Slightly soluble:	Acetonitrile		
Partition coefficient:	3.85		
n-octanol/water:			
Autoignition temperature:	No data available		
Decomposition temperature:	No data available		
Dynamic Viscosity:	No data available		
Kinematic viscosity:	No data available		
9.2 Other safety information	No data available		

9.2 Other safety information

SECTION 10: Stability and reactivity		
10.1 Reactivity	No data available	
10.2 Chemical stability	Stable under proper conditions.	
10.3 Possibility of hazardous reaction	s No special reactivity has been reported.	
10.4 Conditions to avoid	No data available	
10.5 Incompatible materials	Oxidizing agents	

10.6 Hazardous decomposition products Carbon dioxide, Carbon monoxide, Nitrogen oxides (NOx)

SECTION 11: Toxicological information

11.1 Information on toxicological effects	5
Acute Toxicity:	No data available
Skin corrosion/irritation:	No data available
Serious eye damage/irritation:	No data available
Respiratory or skin sensitization:	No data available
Germ cell mutagenicity:	No data available
Carcinogenicity:	
IARC =	No data available
NTP =	No data available
Reproductive toxicity:	No data available
STOT-single exposure:	No data available
STOT-repeated exposure:	No data available
Aspiration hazard:	No data available
RTECS Number:	TX1498230

SECTION 12: Ecological informat	ion
12.1 Toxicity	
Fish:	No data available
Crustacea:	No data available
Algae:	No data available
12.2 Persistence and degradability	No data available
12.3 Bioaccumulative potential	No data available
12.4 Mobility in soil	
Log Pow:	3.85
Soil adsorption (Koc):	No data available
Henry's Law (PaM ³/mol):	8.73 x 10 ⁻⁶
12.5 Results of PBT and vPvB assess	ment
PBT:	Not applicable
vPvB:	Not applicable
12.6 Other adverse effects	No data available
SECTION 13: Disposal considera	tions
13.1 Waste treatment methods	
	sult your local regional authorities. You may be able to dissolve or mix material with a combustible solvent quipped with an afterburner and scrubber system. Observe all federal, state and local regulations when
SECTION 14: Transport informati	on
14.1 UN number	Not listed
14.2 UN proper shipping name	
ADR/RID	Not listed
IMDG/IMO	Not listed
ΙCΑΟ/ΙΑΤΑ	Not listed
14.3 Transport hazard class(es)	
ADR/RID	Does not correspond to the classification standard of the United Nations
IMDG/IMO	Does not correspond to the classification standard of the United Nations
ICAO/IATA	Does not correspond to the classification standard of the United Nations
14.4 Packaging group	
ADR/RID	<u>.</u>
IMDG/IMO	_
ICAO/IATA	
14.5 Environmental hazards	
Marine pollutant	
•	
14.6 Special precautions for user	No data available

14.6 Special precautions for user No data available

SECTION 15: Regulatory information

 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Substance of Very High Concern (SVHC) according to the Not listed REACH Regulations (EC) No.1907/2006
 Not listed

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: Other information	
Prepared by:	TCI EUROPE N.V.
Issue date:	04/09/2019

This SDS was prepared sincerely on the basis of the information we could obtained, however, any warranty shall not be given regarding the data contained and the assessment of hazards and toxicity. Prior to use, please investigate not only the hazards and toxicity information but also the laws and regulations of the organization, area and country where the products are to be used, which shall be given the first priority. The products are supposed to be used promptly after purchase in consideration of safety. Some new information or amendments may be added afterwards. If the products are to be used far behind the expected time of use or you have any questions, please feel free to contact us. The stated cautions are for normal handling only. In case of special handling, sufficient care should be taken, in addition to the safety measures suitable for the situation. All chemical products should be treated with the recognition of "having unknown hazards and toxicity", which differ greatly depending on the conditions and handling when in use and/or the conditions and duration of storage. The products must be handled only by those who are familiar with specialized knowledge and have experience or under the guidance of those specialists throughout use from opening to storage and disposal. Safe usage conditions shall be set up on each user's own responsibility.

End of Safety Data Sheet