

# SAFETY DATA SHEET

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## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

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### Contact information

#### General



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Chemtrec (24-hour availability):  
+1 (800) 424-9300 (USA and Canada)  
+1 (703) 527-3887 (International; collect calls accepted)

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<b>Product identifier</b>	Sofosbuvir/Velpatasvir/Voxilaprevir (400/100/100 mg) Tablets
<b>Synonyms</b>	SOF/VEL/VOX Tablets; SOF/GS-5816/GS-9857 Tablets
<b>Trade names</b>	Vosevi <sup>®</sup>
<b>Chemical family</b>	Mixture
<b>Relevant identified uses of the substance or mixture and uses advised against</b>	Bulk formulated pharmaceutical product/ Formulated pharmaceutical product for research and development purposes; under investigation for treatment of hepatitis C virus (HCV).
<b>Note</b>	This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product.

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## SECTION 2 - HAZARDS IDENTIFICATION

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**Classification of the substance or mixture**      **The classification and labeling listed below is for bulk drug product.**

**Globally Harmonized System [GHS]**      Not classified

**Supplemental**      Mixture not yet fully tested.

### Label elements

**GHS hazard pictogram**      None required

**GHS signal word**      None required

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**SECTION 2 - HAZARDS IDENTIFICATION ...continued**

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**GHS hazard statements** None required

**GHS precautionary statements** None required

**Other hazards** Mixture not fully tested. Oral coadministration of sofosbuvir and velpatasvir for up to 12 weeks was well tolerated in HCV-infected patients. There was a low rate of treatment discontinuation for adverse events (AEs), and a low incidence of serious, severe or life-threatening AEs, and of laboratory abnormalities. Mild to moderate headache was the most commonly reported effect seen with velpatasvir. Similarly, AEs seen in early clinical trials with voxilaprevir were mild and infrequent (most commonly, headache, nausea, and constipation). No clinically significant AEs have been specifically attributed to sofosbuvir in patients treated with other pharmaceutical mixtures containing sofosbuvir.

**Note** This product does not meet criteria for classification under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA). Nevertheless, it should be handled with caution as it contains pharmacologically active ingredients.

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**SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS**

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<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELIN CS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Sofosbuvir	1190307-88-0	N/A	30.8%	Not classified
Cellulose	9004-34-6	232-674-9	19%	Not classified
Voxilaprevir	N/A	N/A	15.4%	Not classified
Velpatasvir	1377049-84-7	N/A	15.4%	CA4: H413
Opadry II Beige	N/A	N/A	3%	Not classified
Magnesium Stearate	557-04-0	209-150-3	1.5%	Not classified

**Note** Sofosbuvir, velpatasvir, and voxilaprevir are listed as they are pharmacologically active. Cellulose and magnesium stearate are listed because they have OELs. Opadry (the coating material) is listed because it contains small amounts of titanium dioxide, a substance considered a possible carcinogen. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of GHS classifications.

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**SECTION 4 - FIRST AID MEASURES**

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**Description of first aid measures**

**Immediate Medical Attention Needed** No. If exposed or concerned: Get medical advice/attention.

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**SECTION 4 - FIRST AID MEASURES ...continued**

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<b>Eye Contact</b>	In the event of a chemical exposure, immediately irrigate eyes with copious quantities of water for at least 15 minutes. Remove contact lenses as soon as practical. Do not delay irrigation while waiting for contact lens removal. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Skin Contact</b>	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Inhalation</b>	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
<b>Ingestion</b>	If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
<b>Protection of first aid responders</b>	See Section 8 for Exposure Controls/Personal Protection recommendations.
<b>Most important symptoms and effects, both acute and delayed</b>	See Sections 2 and 11
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	Medical conditions aggravated by exposure: None known or reported.

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**SECTION 5 - FIREFIGHTING MEASURES**

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<b>Extinguishing media</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
<b>Specific hazards arising from the substance or mixture</b>	No information identified. May emit toxic gases of carbon monoxide, carbon dioxide, oxides of sulfur and nitrogen, and fluorine- or phosphorus-containing compounds.
<b>Flammability/Explosivity</b>	No explosivity or flammability data identified. High concentrations of finely divided airborne organic dust particles can potentially explode if ignited.
<b>Advice for firefighters</b>	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

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**SECTION 6 - ACCIDENTAL RELEASE MEASURES**

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<b>Personal precautions, protective equipment and emergency procedures</b>	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not crush, break or chip tablets. Do not breathe dust.
<b>Environmental precautions</b>	Do not empty into drains. Avoid release to the environment.
<b>Methods and material for containment and cleaning up</b>	If tablets are spilled, scoop up and dispose of in a manner that is compliant with federal, state or local laws. If tablets are crushed or broken, do not raise dust. Clean up spill with HEPA-filtered vacuum if available. If not available, add water to allow for the material to enter solution. Collect material with absorbents. Place spill materials into a leak-proof container suitable for disposal. Decontaminate area a second time. Dispose of material in a manner that is compliant with federal, state and local laws.
<b>Reference to other sections</b>	See Sections 8 and 13 for more information.

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**SECTION 7 - HANDLING AND STORAGE**

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<b>Precautions for safe handling</b>	Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Avoid breathing dust. Wash thoroughly after handling.
<b>Conditions for safe storage including any incompatibilities</b>	Store at 25 °C (77 °F); excursions permitted to 15-30 °C (59-86 °F)
<b>Specific end use(s)</b>	No information identified.

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION**

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**Control  
Parameters/Occupational  
Exposure Limit Values**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Sofosbuvir	Gilead	TWA-8 HR	200 µg/m
Cellulose	ACGIH, Australia, Belgium, Estonia, France, Portugal, Romania, Singapore, Spain	TWA-8 HR	10 mg/m

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**


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**Control  
Parameters/Occupational  
Exposure Limit Values  
...continued**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>	
Cellulose	Ireland, United Kingdom	TWA-8 HR	10 mg/m (inhalable dust); 4 mg/m (respirable dust)	
		STEL	20 mg/m (total inhalable dust)	
	Latvia	TWA-8 HR	2 mg/m	
	Mexico	TWA-8 HR/STEL	10/20 mg/m	
	NIOSH	TWA-8 HR	10 mg/m (total dust); 5 mg/m (respirable dust)	
		OSHA	TWA-8 HR	15 mg/m (total dust); 5 mg/m (respirable fraction)
	United Kingdom	STEL	20 mg/m (inhalable dust); 12 mg/m (respirable dust)	
		Gilead	TWA-8 HR	2 mg/m
	Voxilaprevir	Gilead	TWA-8 HR	70 µg/m
	Velpatasvir	Gilead	TWA-8 HR	70 µg/m
Opadry II Beige	--	--	--	
Magnesium Stearate	ACGIH	TWA-8 HR	10 mg/m (stearates)	
	Lithuania	TWA-8 HR	3 mg/m	
	Sweden	TWA-8 HR	5 mg/m	

**Exposure/Engineering controls**

Control exposures to below the lowest OEL. If tablets are crushed or broken: selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at dust-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling of powders. High-energy operations such as milling or particle sizing should be done within an approved emission control or containment system.

**Respiratory protection**

None required for normal handling of bulk tablets. If tablets are crushed or broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine tablet handling tasks, an approved and properly fitted air-purifying respirator with appropriate HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with appropriate HEPA filters or combination filters or a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection.

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**

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<b>Hand protection</b>	None required for normal handling of bulk tablets. If tablets are crushed or broken: wear nitrile or other impervious gloves if skin contact with tablets is possible. Double gloves may be considered.
<b>Skin protection</b>	None required for normal handling of bulk tablets. If tablets are crushed or broken: wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely or if handling the tablets. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
<b>Eye/face protection</b>	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
<b>Environmental Exposure Controls</b>	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
<b>Other protective measures</b>	Wash hands in the event of contact with this mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**Information on basic physical and chemical properties**

<b>Appearance</b>	Tablets, capsule-shaped, debossed ("GSI" on one side, a square containing the number "3" on the other side), film-coated
<b>Color</b>	Beige
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	Not applicable
<b>Melting point/freezing point</b>	No information identified.
<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued**

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<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapor pressure</b>	No information identified.
<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	No information identified.
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (n-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	Not applicable.
<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular formula</b>	Not applicable (Mixture)
<b>Molecular weight</b>	Not applicable (Mixture)

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**SECTION 10 - STABILITY AND REACTIVITY**

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<b>Reactivity</b>	No information identified.
<b>Chemical stability</b>	Stable when stored as recommended.
<b>Possibility of hazardous reactions</b>	Not expected to occur.
<b>Conditions to avoid</b>	No information identified.
<b>Incompatible materials</b>	No information identified.
<b>Hazardous decomposition products</b>	No information identified.

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**SECTION 11 - TOXICOLOGICAL INFORMATION**

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**Note** No data for this product/mixture were identified. The following data describe the active ingredients and/or the individual ingredients where applicable.

**Information on toxicological effects**

**Route of entry** May be absorbed by inhalation, skin contact and ingestion.

**Acute toxicity**

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Sofosbuvir	--	--	--	--
Cellulose	LC <sub>50</sub>	Inhalation	Rat	>5800 mg/m /4h
	LD <sub>50</sub>	Oral	Rat	>5000 mg/kg
	LD <sub>50</sub>	Dermal	Rabbit	>2000 mg/kg
Voxilaprevir	--	--	--	--
Velpatasvir	--	--	--	--
Opadry II Beige	--	--	--	--
Magnesium Stearate	LC <sub>50</sub>	Inhalation	Rat	>2000 mg/m

**Irritation/Corrosion** Sofosbuvir was considered a non-irritant to skin in an *in vivo* rabbit study and a non-severe irritant to eyes in an *in vitro* eye irritation study.

Mild gastric irritation, which did not adversely affect the animals' health, was seen in repeat-dose studies of voxilaprevir in rats.

**Sensitization** Sofosbuvir was negative in a delayed-type hypersensitivity study in mice.

**STOT-single exposure** Single oral doses of GS-9851 (a near 50:50 mixture of sofosbuvir and its diastereoisomer) up to 1800 mg/kg were well tolerated in rats.

Velpatasvir was well-tolerated in mice, rats and dogs given single oral doses of up to 1000, 600 and 200 mg/kg/day, respectively. Voxilaprevir was well tolerated when given in two single oral doses of up to 2000 mg/kg.

**STOT-repeated exposure/Repeat-dose toxicity** No target organs were identified in rodents treated with sofosbuvir for up to 13 (mice) or 26 (rats) weeks. The NOAEL in the 13-week mouse study was 100/300 (male/female) mg/kg/day. In repeat-dose oral rat studies with sofosbuvir, of up to 26 weeks' duration, effects seen in the longest study were those characteristic of the vehicle. A NOAEL identified in this study was 500 mg/kg/day.

Sofosbuvir was also administered orally to dogs, for up to 39 weeks with the gastrointestinal tract and hematopoietic system identified as target organs. The NOAEL was 100 mg/kg/day.

Velpatasvir was well-tolerated in rats; there were no treatment-related effects on clinical observations, body weight, food consumption, ophthalmic observations, or clinical and anatomic pathology and no test-article related deaths, at up to 200 mg/kg/day (a NOEL) for 26 weeks.



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**SECTION 11 - TOXICOLOGICAL INFORMATION ...continued**

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**STOT-repeated exposure/Repeat-dose toxicity ...continued**

No velpatasvir-related changes on mortality, body weight/body weight gain, food consumption and no ophthalmic, ECG, clinical, or anatomical pathology findings were observed in a 39-week oral study in dogs, at doses up to 100 mg/kg/day (NOAEL).

Voxilaprevir was well tolerated in rats and dogs in 13-week oral studies. NOAELs of 100 and 15 mg/kg/day, respectively (the highest doses tested), were identified.

**Reproductive toxicity**

Sofosbuvir administered at oral doses up to 500 mg/kg/day had no adverse effects on mating, fertility and embryo survival in rats.

No significant effects were noted in reproductive toxicity studies with velpatasvir. In a rat fertility study, the NOEL for reproductive parameters was 200 mg/kg/day. No definitive reproductive toxicity studies for voxilaprevir were identified.

**Developmental toxicity**

There were no adverse effects on embryo-fetal development seen in rats and rabbits following oral administration of 500 and 300 mg/kg/day sofosbuvir, 200 and 300 mg/kg/day velpatasvir, and 100 and 300 mg/kg/day voxilaprevir, respectively.

**Genotoxicity**

Sofosbuvir was negative in the Ames bacterial cell mutagenicity screening assay, in a chromosomal aberration assay using unspecified mammalian cells, and in an *in vivo* mouse micronucleus assay.

Velpatasvir and voxilaprevir were both negative in an Ames bacterial cell mutagenicity assay, a chromosomal aberration assay, and an *in vivo* rat bone marrow micronucleus assay.

**Carcinogenicity**

Sofosbuvir was not carcinogenic in two-year studies in mice and rats, at dose levels up to 600 and 750 mg/kg/day, respectively. Carcinogenicity studies with velpatasvir or voxilaprevir were not identified.

The coating material used in this product contains titanium dioxide, a chemical that is classified by IARC as a Group 2B agent (possibly carcinogenic to humans) and by the NTP as Known to Cause Cancer. It is also considered a carcinogen by NIOSH and by ACGIH as Not Classifiable (A4). None of the other components of the mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

**Aspiration hazard**

No data available.

**Human health data**

See "Section 2 - Other Hazards"

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**SECTION 12 - ECOLOGICAL INFORMATION**


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**Toxicity**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Sofosbuvir	--	--	--
Cellulose	--	--	--
Voxilaprevir	NOEC (growth inhibition)	Pimephales promelas (fathead minnow)	11 mg/L
	NOEC/21 days (repro)	Daphnia Magna	6.2 mg/L
	NOEC (72h) (yield, biomass, growth rate)	Pseudokirchneriella Subcapitata (Algae)	20 mg/L
	NOEL (3 hour, respiration inhibition)	Activated sludge microorganisms	1000 mg/L
Velpatasvir	EC <sub>50</sub> /21-day survival	Daphnia Magna	>0.017 mg/L
	NOEC (21-day survival)	Daphnia Magna	0.017 mg/L
	LOEC (21-day survival)	Daphnia Magna	>0.017 mg/L
	EC <sub>50</sub> /21-day reproduction	Daphnia Magna	0.012 mg/L
	NOEC (21-day reproduction)	Daphnia Magna	0.0066 mg/L
	LOEC (21-day reproduction)	Daphnia Magna	0.017 mg/L
	NOEC/28 days (hatch, post-hatch, growth)	Pimephales promelas (fathead minnow)	0.2 mg/L
	LOEC/28 days (hatch, post-hatch, growth)	Pimephales promelas (fathead minnow)	>0.2 mg/L
	ErC <sub>50</sub> /EbC <sub>50</sub>	Pseudokirchneriella subcapitata (Algae)	>0.049 mg/L
	NOEC (72h) (yield, biomass, growth rate)	Pseudokirchneriella subcapitata	0.049 mg/L

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**SECTION 12 - ECOLOGICAL INFORMATION ...continued**


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**Toxicity ...continued**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Velpatasvir	EC <sub>10</sub> (3h respiratory inhibition test)	Activated sludge microorganisms	≥1000 mg/L
	NOEC (3h respiratory inhibition test)	Activated sludge microorganisms	≥105 mg/L
Opadry II Beige	--	--	--
Magnesium Stearate	--	--	--

**Additional toxicity information**

Environmental fate and effects testing has been performed on GS-331007, a major excretory metabolite and nucleoside of sofosbuvir (comprising roughly 80% of an administered dose) that is pharmacologically inactive. The following results were obtained:

GS-331007 did not inhibit respiration of activated sludge microorganisms at a concentration of 1000 mg/L.

In an early life cycle study in fathead minnows, the No-Observed-Effect-Concentration (NOEC) was ≥10 mg/L.

In a daphnia reproduction study, the 21 day NOEC for immobilization, reproduction and growth, was determined to be 26 mg/L.

GS-331007 did not have a significant effect on algal growth rate. Results of the environmental fate studies indicated that it would not be significantly degraded in sewage treatment facilities, or be removed from the aqueous phase *via* sorption to sewage biosolids.

**Persistence and Degradability**

Sofosbuvir (as GS-331007):  
System DT<sub>50</sub> (dissipation): 60-66 days  
System DT<sub>50</sub> (degradation): >100 days

Velpatasvir is not considered to be readily biodegradable:  
System DT<sub>50</sub>: 62.4-99.9 days  
Sediment DT<sub>50</sub> 109-136 days in sediment @ 20 °C

Voxilaprevir is not considered to be readily biodegradable:  
System DT<sub>50</sub>: 30-76 days

**Bioaccumulative potential**

Sofosbuvir: -0.417 (pH 4); 0.576 (pH 7); -1.28 (pH 9)  
Velpatasvir - Log D 6.31 (pH 8)  
Voxilaprevir (*n*-Octanol/Water log K<sub>OW</sub> of ~4.3 @ pH 7)

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**SECTION 12 - ECOLOGICAL INFORMATION ...continued**

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<b>Mobility in soil</b>	<p>The environmentally relevant residues of sofosbuvir (as GS-331007) and velpatasvir have distinctly different fates in the environment. While sofosbuvir tends to remain in aqueous phase, velpatasvir dissipates rapidly in water but is somewhat persistent in sediment. However, although velpatasvir is considered to be somewhat persistent in sediment, it is indicated to have sufficiently low concentrations in the sediment environment that its toxicity is unlikely to present a risk to aquatic ecosystems. The PNEC in sediment was 41.43 mg/kg<sub>dwt</sub><sup>-1</sup>. Sediment degradation data suggests that these residues partition (to different degrees) to sediment (e.g., &gt;10% applied radioactivity shifted after 14 days).</p> <p>The adsorption coefficient of voxilaprevir is sufficiently high to suggest that it will potentially reach the terrestrial soil environment, through the route of spreading sewage sludge on agricultural land, and is unlikely to be emitted to receiving surface waters. If voxilaprevir is emitted to surface water it is likely to steadily partition into sediment. In a degradation study, voxilaprevir displayed a significant shift to sediment (&gt; 10% AR in sediment at or after Day 14). Once in municipal sewage treatment facilities, voxilaprevir will not be rapidly degraded and is likely to bind to sewage solids, which are removed after settling.</p>
<b>Results of PBT and vPvB assessment</b>	<p>Voxilaprevir and sofosbuvir (as GS-331007) are not considered to be PBT substances.</p> <p>Velpatasvir: Persistence - P fulfilled Bioaccumulation - Possibly B Toxicity - T fulfilled</p>
<b>Other adverse effects</b>	<p>The environmentally relevant residues of sofosbuvir, velpatasvir, and voxilaprevir are essentially non-toxic to sewage microbes and will likely not interfere with the normal operation of sewage treatment facilities.</p>
<b>Note</b>	<p>The environmental characteristics of this mixture have not been fully investigated. The above data are for the active ingredient and/or any other ingredient(s) where applicable. Releases to the environment should be avoided.</p>

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**SECTION 13 - DISPOSAL CONSIDERATIONS**

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<b>Waste treatment methods</b>	<p>Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.</p>
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**SECTION 14 - TRANSPORT INFORMATION**

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<b>Transport</b>	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
<b>UN number</b>	None assigned.
<b>UN proper shipping name</b>	None assigned.
<b>Transport hazard classes and packing group</b>	None assigned.
<b>Environmental hazards</b>	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
<b>Special precautions for users</b>	Mixture not fully tested - avoid exposure.
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.

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**SECTION 15 - REGULATORY INFORMATION**

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<b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
<b>Chemical safety assessment</b>	Not conducted.
<b>TSCA status</b>	This product/mixture contains chemical(s) that are listed on the TSCA inventory.
<b>SARA section 313</b>	Not listed.
<b>California proposition 65</b>	This product contains titanium dioxide, which is listed as a potential carcinogen under Proposition 65.
<b>Additional information</b>	No other information identified.

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**SECTION 16 - OTHER INFORMATION**

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<b>Full text of H phrases and GHS classifications</b>	CA4 - Chronic Aquatic Toxicity Category 4. H413 - May cause long-lasting harmful effects to aquatic life.
<b>Sources of data</b>	Information from published literature and internal company data.

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**SECTION 16 - OTHER INFORMATION ...continued**

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**Abbreviations** ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

**Issue Date** 19 July 2017

**Revisions** This is the third version of this SDS.

**Disclaimer** The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.